



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

HEALGEN SCIENTIFIC LLC
C/O JOE SHIA
LSI INTERNATIONAL
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20877

September 9, 2015

Re: K152269

Trade/Device Name: Healgen Amphetamine Test (Strip, Cassette, Cup, Dip Card), Healgen Cocaine Test (Strip, Cassette, Cup, Dip Card), Healgen Methamphetamine Test (Strip, Cassette, Cup, Dip Card)

Regulation Number: 21 CFR 862.3100

Regulation Name: Amphetamine Test System

Regulatory Class: II

Product Code: DKZ, DIO, LAF

Dated: July 26, 2015

Received: August 11, 2015

Dear Mr. Joe 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 (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 regulation (21 CFR Part 801), 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" (21CFR 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,

Courtney H. Lias -S

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

Indications for Use

510(k) Number (if known)
k152269

Device Name

Healgen Amphetamine Test (Strip, Cassette, Cup, Dip Card)
Healgen Cocaine Test (Strip, Cassette, Cup, Dip Card)
Healgen Methamphetamine Test (Strip, Cassette, Cup, Dip Card)

Indications for Use (Describe)

Healgen Amphetamine Test is an immunochromatographic assay for the qualitative determination of Amphetamine 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 Cocaine Test is an immunochromatographic assay for the qualitative determination of Benzoylcegonine in human urine at a Cut-Off concentration of 150 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 Methamphetamine Test is an immunochromatographic assay for the qualitative determination of Methamphetamine 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.

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: September 1, 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 Amphetamine Test (Strip, Cassette, Cup, Dip Card)
Healgen Cocaine Test (Strip, Cassette, Cup, Dip Card)
Healgen Methamphetamine Test (Strip, Cassette, Cup, Dip Card)

Classification: Class II

Product Code	CFR #	Panel
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
LAF	21 CFR, 862.3610 Methamphetamine Test System	Toxicology

- 5. Predicate Devices:
K122809
Advin Multi-Drug Screen Test.
- 6. Intended Use / Indications for Use
Healgen Amphetamine Test is an immunochromatographic assay for the qualitative determination of Amphetamine 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 Cocaine Test is an immunochromatographic assay for the qualitative determination of Benzoylcegonine in human urine at a Cut-Off concentration of 150 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 Methamphetamine Test is an immunochromatographic assay for the qualitative determination of Methamphetamine 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.

7. Device Description

Healgen Amphetamine Test, Healgen Cocaine Test and Healgen Methamphetamine Test are immunochromatographic assays for Amphetamine, Cocaine and Methamphetamine. Each assay test is a lateral flow system for the qualitative detection of Amphetamine, Benzoylcegonine and Methamphetamine (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 Amphetamine Test, Healgen Cocaine Test and Healgen Methamphetamine Test and the predicate device is provided in Table 1, Table 2 and Table 3.

Table 1: Features Comparison of Healgen Amphetamine Test and the Predicate Device

Item	Device	Predicate – k122809
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Amphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on	Same

Item	Device	Predicate – k122809
	the principle of antigen antibody immunochemistry.	
Specimen Type	Human Urine	Same
Cut-Off Values	500 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	Same
Configurations	Strip, Cassette, Cup, Dip Card	Cassette, Cup, DipCard

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

Item	Device	Predicate – k122809
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Benzoylcegonine	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	150 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	Same
Configurations	Strip, Cassette, Cup, Dip Card	Cassette, Cup, DipCard

Table 3: Features Comparison of Healgen Methamphetamine Test and the Predicate Device

Item	Device	Predicate – k122809
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	METHAMPHETAMINE	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody	Same

Item	Device	Predicate – k122809
	immunochemistry.	
Specimen Type	Human Urine	Same
Cut-Off Values	500 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	Same
Configurations	Strip, Cassette, Cup, Dip Card	Cassette, Cup, DipCard

9. Test Principle

Healgen Amphetamine Test, Healgen Cocaine Test and Healgen Methamphetamine Test are rapid tests for the qualitative detection of Amphetamine, Benzoylcegonine and Methamphetamine 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-off concentration 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:

Amphetamine Strip Format

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								

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 1	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	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+	50-/0+	26-/24+	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 1	50-/0+	50-/0+	50-/0+	50-/0+	33-/17+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	31-/19+	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 1	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	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 1	50-/0+	50-/0+	50-/0+	50-/0+	32-/18+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	32-/18+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	30-/20+	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine

Strip 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 1	50-/0+	50-/0+	50-/0+	50-/0+	17-/33+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	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-

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 1	50-/0+	50-/0+	50-/0+	50-/0+	32-/18+	50+/0-	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-

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 3	50-/0+	50-/0+	50-/0+	50-/0+	32-/18+	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 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-

CUPFormat

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 1	50-/0+	50-/0+	50-/0+	50-/0+	31-/19+	50+/0-	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+	50-/0+	30-/20+	50+/0-	50+/0-	50+/0-	50+/0-

METHAMPHETAMINE

Strip 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 1	50-/0+	50-/0+	50-/0+	50-/0+	34-/16+	50+/0-	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+	33-/17+	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 1	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	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 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	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-

CUPFormat

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 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	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-

b. Linearity

Not applicable.

c. Stability

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

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 Amphetamine, Cocaine and Methamphetamine. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Amphetamine Test	Amphetamine	500
Cocaine Test	Benzoyllecgonine	150
Methamphetamine Test	Methamphetamine	500

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.

Amphetamine

Acetophenetidin	R(-)-Epinephrine	Pentobarbital
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N-Acetylprocainamide	Erythromycin	Perphenazine
Acetylsalicylic Acid (Aspirin)	Estrone-3-sulfate	Phencyclidine
Alphenal	Ethyl-p-aminobenzoate	Phenelzine
Amobarbital	Fenoprofen	Phenobarbital
Aminopyrine	Furosemide	Phenylephrine-L
Amitriptyline	Gentisic acid	Phenylethylamine
Amoxicillin	Hemoglobin	Phenylpropanolamine
Ampicillin(Ampicillin)	Hydralazine	Prednisolone Acetate
Aprobarbital	(+/-)-4-Hydroxyamphetamine HCL	Prednisone
Apomorphine	Hydrochlorothiazide	Procaine(Novocaine)
L-Ascorbic Acid	Hydrocodone	Promazine
Aspartame	Hydrocortisone	Promethazine
Atropine	a -Hydroxyhippuric acid	Propoxyphene,d-
Butabarbital	p-Hydroxymethamphetamine	Propranolol
Butalbital	Ibuprofen	Pseudoephedrine HCL
Butethal	Imipramine	Quinidine
Benzilic acid	Isoxsuprine	Quinine
Benzphetamine	Isoproterenol(+/-)	Ranitidine(Zantac)
Bezoic Acid	Ketamine	Salicylic Acid
Bilirubin	Labetalol	Secobarbital
Caffeine	Levorphanol	Serotonin
Chloramphenicol	Loperamide	Sulfamethazine
Chlordiazepoxide HCL	Maprotiline	Sulindac
Chloroquine	Meprobamate	Temazepam
Chlorothiazide	Methadone	11-Nor- Δ 9-Tetrahydrocannabinol
Chlorpheniramine	Methoxyphenamine	Tetracycline
Chlorpromazine	Methylphenidate	Tetrahydrozoline
Cholesterol	Nalbuphine	Thiamine
Clomipramine	Nalidixic acid	L-Thyroxine
Clonidine hydrochloride	Naloxone hydrochloride	ThioridazineHydrochloride
Cortisone	Naltrexone hydrochloride	Triamterene
Cotinine(-)	Naproxen	Triflupromazine Hydrochloride
Creatinine	Niacinamide	Trimethoprim
Cyclopentobarbital	Nifedipine	Trimipramine
Deoxyepinephrine	Norethindrone	Tryptamine
Dextromethorphan	Norpropoxyphene	DL-Tryptophan

Diazepam	Noscapine	Tyramine
Diflunisal	Oxazepam	D/L-Tyrosine
Digoxin	Oxymetazoline	Uric Acid
Doxylamine	Papaverine	Verapamil
Ecgonine methylester	Penicillin	Zomepirac

Cocaine

Acetophenetidin	Doxylamine	Phentermine
N-Acetylprocainamide	R(-)-Epinephrine	Pentobarbital
Acetylsalicylic Acid (Aspirin)	Erythromycin	Perphenazine
Alphenal	Estrone-3-sulfate	Phencyclidine
Amobarbital	Ethyl-p-aminobenzoate	Phenelzine
Aminopyrine	Fenoprofen	Phenobarbital
Amitriptyline	Furosemide	Phenylephrine-L
Amoxicillin	Gentisic acid	Phenylethylamine
Amphetamine Sulfate	Hemoglobin	Phenylpropanolamine
Ampicillin(Ampicillin)	Hydralazine	Prednisolone Acetate
Aprobarbital	(+/-)-4-Hydroxyamphetamine HCL	Prednisone
Apomorphine	Hydrochlorothiazide	Procaine(Novocaine)
d-amphetamine	Hydrocodone	Promazine
D,l-amphetamine	Hydrocortisone	Promethazine
l-amphetamine	a -Hydroxyhippuric acid	Propoxyphene,d-
L-Ascorbic Acid	p-Hydroxymethamphetamine	Propranolol
Aspartame	Ibuprofen	Pseudoephedrine HCL
Atropine	Imipramine	Quinidine
Butabarbital	Isoxsuprine	Quinine
Butalbital	Isoproterenol-(+/-)	Ranitidine(Zantac)
Butethal	Ketamine	Salicylic Acid
Benzilic acid	Labetalol	Secobarbital
Benzphetamine	Levorphanol	Serotonin
Bezoic Acid	Loperamide	Sulfamethazine
Bilirubin	Maprotiline	Sulindac
Caffeine	Meprobamate	Temazepam
Chloramphenicol	Methadone	11-Nor- Δ 9-Tetrahydrocannabinol
Chlordiazepoxide HCL	Methoxyphenamine	Tetracycline
Chloroquine	Methylphenidate	Tetrahydrozoline

Chlorothiazide	(+/-)-Methylenedioxymphetamine (MDA)	Thiamine
Chlorpheniramine	Nalbuphine	L-Thyroxine
Chlorpromazine	Nalidixic acid	ThioridazineHydrochloride
Cholesterol	Naloxone hydrochloride	Triamterene
Clomipramine	Naltrexone hydrochloride	Triflupromazine Hydrochloride
Clonidine hydrochloride	Naproxen	Trimethoprim
Cortisone	Niacinamide	Trimipramine
Cotinine(-)	Nifedipine	Tryptamine
Creatinine	Norethindrone	DL-Tryptophan
Cyclopentobarbital	Norpropoxyphene	Tyramine
Deoxyepinephrine	Noscapine	D/L-Tyrosine
Dextromethorphan	Oxazepam	Uric Acid
Diazepam	Oxymetazoline	Verapamil
Diflunisal	Papaverine	Zomepirac
Digoxin	Penicillin	

METHAMPHETAMINE

Acetophenetidin	R(-)-Epinephrine	Pentobarbital
N-Acetylprocainamide	Erythromycin	Perphenazine
Acetylsalicylic Acid (Aspirin)	Estrone-3-sulfate	Phencyclidine
Alphenal	Ethyl-p-aminobenzoate	Phenelzine
Amobarbital	Fenoprofen	Phenobarbital
Aminopyrine	Furosemide	Phenylpropanolamine
Amitriptyline	Gentisic acid	Prednisolone Acetate
Amoxicillin	Hemoglobin	Prednisone
Ampicillin(Ampicillin)	Hydralazine	Procaine(Novocaine)
Aprobarbital	(+/-)-4-Hydroxyamphetamine HCL	Promazine
Apomorphine	Hydrochlorothiazide	Promethazine
L-Ascorbic Acid	Hydrocodone	Propoxyphene,d-
Aspartame	Hydrocortisone	Propranolol
Atropine	a -Hydroxyhippuric acid	Pseudoephedrine HCL
Butabarbital	Ibuprofen	Quinidine
Butalbital	Imipramine	Quinine
Butethal	Isoxsuprine	Ranitidine(Zantac)
Benzilic acid	Isoproterenol(+/-)	Salicylic Acid
Benzphetamine	Ketamine	Secobarbital

Bezoic Acid	Labetalol	Serotonin
Bilirubin	Levorphanol	Sulfamethazine
Caffeine	Loperamide	Sulindac
Chloramphenicol	Maprotiline	Temazepam
Chlordiazepoxide HCL	Meprobamate	11-Nor- Δ 9-Tetrahydrocannabinol
Chlorothiazide	Methadone	Tetracycline
Chlorpheniramine	Methoxyphenamine	Tetrahydrozoline
Chlorpromazine	Methylphenidate	Thiamine
Cholesterol	Nalbuphine	L-Thyroxine
Clomipramine	Nalidixic acid	ThioridazineHydrochloride
Clonidine hydrochloride	Naloxone hydrochloride	Triamterene
Cortisone	Naltrexone hydrochloride	Triflupromazine Hydrochloride
Cotinine(-)	Naproxen	Trimethoprim
Creatinine	Niacinamide	Trimipramine
Cyclopentobarbital	Nifedipine	Tryptamine
Deoxyepinephrine	Norethindrone	DL-Tryptophan
Dextromethorphan	Norpropoxyphene	Tyramine
Diazepam	Noscapine	D/L-Tyrosine
Diflunisal	Oxazepam	Uric Acid
Digoxin	Oxymetazoline	Verapamil
Doxylamine	Papaverine	Zomepirac
Ecgonine methylester	Penicillin	

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.

Amphetamine (Cut-off=500 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
D-Amphetamine	500	100%
D,L-Amphetamine	750	67%
L-Amphetamine	16000	3%
Phentermine	650	77%

(+/-)-Methylenedioxyamphetamine (MDA)	800	63%
d-Methamphetamine	>100,000	<0.5%
l-Methamphetamine	>100,000	<0.5%
ephedrine	>100,000	<0.5%
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000	<0.5%
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000	<0.5%

Cocaine (Cut-off=150 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Benzoylcegonine	150	100%
Cocaethylene	2500	6%
Cocaine	500	30%
Ecgonine	12,500	1.2%
Ecgonine methylester	50,000	0.3%

Methamphetamine (Cut-off=500 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
d-Methamphetamine	500	100%
Methylenedioxyamphetamine (MDA)	1000	50%
p-Hydroxymethamphetamine	15000	3%
l-Methamphetamine	4000	13%
Mephentermine	25000	2%
d,l-Amphetamine	75000	0.7%
(1R,2S)-(-)-Ephedrine	50000	1%
β-Phenylethylamine	75000	0.7%
Methylenedioxyamphetamine (MDMA)	1000	50%
Methylenedioxy-n-ethylamphetamine (MDEA)	20000	2.5%
d-Amphetamine	50000	1%
Chloroquine	12500	4%
l-Phenylephrine	100000	0.5%

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 Amphetamine Test, the Cocaine Test and the Methamphetamine 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:

Amphetamine

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	15	24
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of Amphetamine Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	AMP68	531	Negative
Viewer B	AMP68	531	Negative
Viewer C	AMP68	531	Negative
Viewer C	AMP63	504	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	15	24
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	15	24
	Negative	10	15	15	1	0

Discordant Results of Amphetamine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	AMP68	531	Negative
Viewer A	AMP63	504	Negative
Viewer B	AMP68	531	Negative
Viewer C	AMP68	531	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	14	24
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	15	24
	Negative	10	15	15	1	0

Discordant Results of Amphetamine Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	AMP68	531	Negative
Viewer A	AMP63	504	Negative
Viewer B	AMP68	531	Negative
Viewer B	AMP63	504	Negative
Viewer C	AMP68	531	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%)
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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	14	24
	Negative	10	15	15	2	0

Discordant Results of Amphetamine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	AMP68	531	Negative
Viewer A	AMP63	504	Negative
Viewer B	AMP68	531	Negative
Viewer C	AMP68	531	Negative
Viewer C	AMP63	504	Negative

Cocaine

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	14	24
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	15	24
	Negative	10	15	15	1	0

Discordant Results of Cocaine Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	COC68	171	Negative
Viewer A	COC69	164	Negative
Viewer B	COC68	171	Negative
Viewer B	COC71	187	Negative
Viewer C	COC69	164	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	15	24
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of Cocaine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	COC69	164	Negative
Viewer B	COC68	171	Negative
Viewer C	COC68	171	Negative
Viewer C	COC69	164	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	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of Cocaine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	COC68	171	Negative
Viewer A	COC69	164	Negative
Viewer B	COC68	171	Negative
Viewer B	COC03	182	Negative

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer C	COC68	171	Negative
Viewer C	COC69	164	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	15	24
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	15	24
	Negative	10	15	15	1	0

Discordant Results of Cocaine Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	COC68	171	Negative
Viewer B	COC68	171	Negative
Viewer C	COC69	164	Negative

Methamphetamine

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	15	24
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of Methamphetamine Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
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Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	MET64	501	Negative
Viewer B	MET64	501	Negative
Viewer C	MET64	501	Negative
Viewer C	MET62	504	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	15	24
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of Methamphetamine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	MET64	501	Negative
Viewer B	MET64	501	Negative
Viewer C	MET64	501	Negative
Viewer C	MET62	504	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	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	15	24
	Negative	10	15	15	1	0

Discordant Results of Methamphetamine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	MET64	501	Negative
Viewer A	MET70	517	Negative
Viewer B	MET64	501	Negative
Viewer B	MET62	504	Negative
Viewer C	MET64	501	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	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	15	24
	Negative	10	15	15	1	0

Discordant Results of Methamphetamine Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	MET25	509	Negative
Viewer A	MET64	501	Negative
Viewer B	MET64	501	Negative
Viewer C	MET64	501	Negative

Lay-user study

A lay user study was performed at three intended user sites with 560 lay persons testing each of the Amphetamine, the Cocaine and the Methamphetamine devices. Total of 1680 individuals performed the study. A total of 214 females and 346 males tested the Amphetamine samples, 196 females and 364 males tested the Cocaine samples and 205 females and 355 males tested the Methamphetamine 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 (Amphetamine Strip)

% of Cutoff	Number of samples	AMP 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 (Amphetamine Cassette)

% of Cutoff	Number of samples	AMP 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	2	18	90%
+25% Cutoff	20	625	18	2	90%
+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	0	100%

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

% of Cutoff	Number of samples	AMP 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 (Amphetamine Cup)

% of Cutoff	Number	AMP Concentration by	Lay person results	The
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	of samples	GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-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 (Cocaine Strip)

% of Cutoff	Number of samples	COC 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	37.5	0	20	100%
-50% Cutoff	20	75	0	20	100%
-25% Cutoff	20	112.5	1	19	95%
+25% Cutoff	20	187.5	19	1	95%
+50% Cutoff	20	225	20	0	100%
+75% Cutoff	20	262.5	20	0	100%

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

% of Cutoff	Number of samples	COC 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	37.5	0	20	100%
-50% Cutoff	20	75	0	20	100%
-25% Cutoff	20	112.5	2	18	90%
+25% Cutoff	20	187.5	19	1	95%
+50% Cutoff	20	225	20	0	100%
+75% Cutoff	20	262.5	20	0	100%

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

% of Cutoff	Number	COC Concentration by	Lay person results	The
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	of samples	GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	37.5	0	20	100%
-50% Cutoff	20	75	0	20	100%
-25% Cutoff	20	112.5	2	18	90%
+25% Cutoff	20	187.5	18	2	90%
+50% Cutoff	20	225	20	0	100%
+75% Cutoff	20	262.5	20	0	100%

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

% of Cutoff	Number of samples	COC 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	37.5	0	20	100%
-50% Cutoff	20	75	0	20	100%
-25% Cutoff	20	112.5	1	19	95%
+25% Cutoff	20	187.5	19	1	95%
+50% Cutoff	20	225	20	0	100%
+75% Cutoff	20	262.5	20	0	100%

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

% of Cutoff	Number of samples	MET 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	2	18	90%
+25% Cutoff	20	625	18	2	90%
+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	0	100%

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

% of Cutoff	Number	MET Concentration by	Lay person results	The
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	of samples	GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-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 (Methamphetamine DipCard)

% of Cutoff	Number of samples	MET 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	2	18	90%
+25% Cutoff	20	625	18	2	90%
+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	0	100%

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

% of Cutoff	Number of samples	MET 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	2	18	90%
+25% Cutoff	20	625	18	2	90%
+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	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 Amphetamine Test, Healgen Cocaine Test and Healgen Methamphetamine Test are substantially equivalent to the predicate.