



Food and Drug Administration
10903 New Hampshire Avenue
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August 18, 2015

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

Re: K151348

Trade/Device Name: Healgen Propoxyphene Test (Strip, Cassette, Cup, Dip Card), Healgen Nortriptyline Test (Strip, Cassette, Cup, Dip Card), Healgen EDDP (Methadone Metabolite) Test (Strip, Cassette, Cup, Dip Card)

Regulation Number: 21 CFR 862.3910

Regulation Name: Tricyclic antidepressant drugs test system

Regulatory Class: II

Product Code: LFG, DJR, JXN

Dated: July 6, 2015

Received: July 9, 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,

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)
k151348

Device Name

Healgen Propoxyphene Test (Strip, Cassette, Cup, Dip Card)

Healgen Nortriptyline Test (Strip, Cassette, Cup, Dip Card)

Healgen EDDP (Methadone Metabolite) Test (Strip, Cassette, Cup, Dip Card)

Indications for Use (Describe)

Healgen Propoxyphene Test is an immunochromatographic assay for the qualitative determination of Propoxyphene in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when the prescription drug Propoxyphene is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Propoxyphene in urine. 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 Nortriptyline Test is an immunochromatographic assay for the qualitative determination of Nortriptyline in human urine at a Cut-Off concentration of 1000 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when the prescription drug Nortriptyline is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Nortriptyline in urine. 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 EDDP (Methadone Metabolite) Test is an immunochromatographic assay for the qualitative determination of EDDP (2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine) in human urine at a Cut-Off concentration of 300 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: July 6, 2015
2. Submitter: HEALGEN SCIENTIFIC LLC
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4. Device Name: Healgen Propoxyphene Test (Strip, Cassette, Cup, Dip Card)
Healgen Nortriptyline Test (Strip, Cassette, Cup, Dip Card)
Healgen EDDP (Methadone Metabolite) Test (Strip, Cassette, Cup, Dip Card)

Classification: Class II

Product Code	CFR #	Panel
JXN	21 CFR, 862.3700 Propoxyphene Test System	Toxicology
DJR	21 CFR, 862.3620 Methadone Test System	Toxicology
LFG	21 CFR, 862.3910 Tricyclic antidepressant drugs test system Test System	Toxicology

5. Predicate Devices:
k140748
Co-Innovation Biotech One Step Single/Multi-drug Test.
6. Intended Use / Indications for Use
Healgen Propoxyphene Test is an immunochromatographic assay for the qualitative determination of Propoxyphene in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when the prescription drug Propoxyphene is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Propoxyphene in urine. 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 Nortriptyline Test is an immunochromatographic assay for the qualitative determination of Nortriptyline in human urine at a Cut-Off concentration of 1000 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when the prescription drug Nortriptyline is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Nortriptyline in urine. 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 EDDP (Methadone Metabolite) Test is an immunochromatographic assay for the qualitative determination of EDDP (2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine) in human urine at a Cut-Off concentration of 300 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 Propoxyphene Test, Healgen Nortriptyline Test and Healgen EDDP (Methadone Metabolite) Test are immunochromatographic assays for Propoxyphene, Nortriptyline and EDDP. Each assay test is a lateral flow system for the qualitative detection of Propoxyphene, Nortriptyline and EDDP (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 Propoxyphene Test, Healgen Nortriptyline Test and Healgen EDDP (Methadone Metabolite) Test and the predicate device is provided in Table 1, Table 2 and Table 3.

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

Item	Device	Predicate – k140748
Intended Use	For the qualitative determination of Propoxyphene in human urine.	Same
Drug Analyte	Propoxyphene	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	300 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	Same
Configurations	Strip, Cassette, Cup, Dip Card	Cup

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

Item	Device	Predicate – k140748
Intended Use	For the qualitative determination of Nortriptyline in human urine.	Same
Drug Analyte	Nortriptyline	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	1000 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	Same
Configurations	Strip, Cassette, Cup, Dip Card	Cup

Table 3: Features Comparison of Healgen EDDP (Methadone Metabolite) Test and the Predicate Device

Item	Device	Predicate – k140748
Intended Use	For the qualitative determination of EDDP in human urine.	Same
Drug Analyte	EDDP	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	300 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	Same
Configurations	Strip, Cassette, Cup, Dip Card	Cup

9. Test Principle

Healgen Propoxyphene Test, Healgen Nortriptyline Test and Healgen EDDP (Methadone Metabolite) Test are rapid tests for the qualitative detection of Propoxyphene, Nortriptyline and EDDP 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:

Propoxyphene**Strip Format**

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	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+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	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+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	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+	21-/29+	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-

Nortriptyline**Strip Format**

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	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+	24-/26+	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-

Cassette Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/-	50+/-	50+/-	50+/-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/-	50+/-	50+/-	50+/-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/-	50+/-	50+/-	50+/-

Dip Card Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/-	50+/-	50+/-	50+/-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/-	50+/-	50+/-	50+/-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/-	50+/-	50+/-	50+/-

CUP Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/-	50+/-	50+/-	50+/-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/-	50+/-	50+/-	50+/-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/-	50+/-	50+/-	50+/-

EDDP

Strip Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/-	50+/-	50+/-	50+/-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/-	50+/-	50+/-	50+/-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/-	50+/-	50+/-	50+/-

Cassette Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/-	50+/-	50+/-	50+/-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/-	50+/-	50+/-	50+/-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/-	50+/-	50+/-	50+/-

Dip Card Format

Drug \ Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
	Cut-off	Cut-off	Cut-off	Cut-off		Cut-off	Cut-off	Cut-off	Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/-	50+/-	50+/-	50+/-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/-	50+/-	50+/-	50+/-

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+	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 1	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	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 Propoxyphene, Nortriptyline and EDDP. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Propoxyphene Test	Propoxyphene	300
Nortriptyline Test	Nortriptyline	1000
EDDP Test	EDDP	300

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.

Propoxyphene

Acetophenetidin	Ethyl-p-aminobenzoate	Perphenazine
N-Acetylprocainamide	Fenoprofen	Phencyclidine
Acetylsalicylic Acid (Aspirin)	Furosemide	Phenelzine
Aminopyrine	Gentisic acid	Phenobarbital
Amitriptyline	Hemoglobin	Phentermine
Amoxicillin	Hydralazine	Phenylephrine-L
Amobarbital	(+/-)-4-Hydroxyamphetamine HCL	Phenylethylamine
D-Amphetamine	Hydrochlorothiazide	Phenylpropanolamine
L-Amphetamine	Hydrocodone	Prednisolone Acetate
Amphetamine Sulfate	Hydrocortisone	Prednisone
Ampicillin(Ampicillin)	a -Hydroxyhippuric acid	Procaine(Novocaine)
Apomorphine	p-Hydroxymethamphetamine	Promazine
L-Ascorbic Acid	Ibuprofen	Promethazine
Aspartame	Imipramine	Propranolol
Atropine	Isoxsuprine	Pseudoephedrine HCL
Benzilic acid	Isoproterenol-(+/-)	Quinidine
Benzphetamine	Ketamine	Quinine
Bezoic Acid	Labetalol	Ranitidine(Zantac)
Bilirubin	Levorphanol	Salicylic Acid
Caffeine	Loperamide	Secobarbital
Chloramphenicol	Maprotiline	Serotonin
Chlordiazepoxide HCL	Meprobamate	Sulfamethazine
Chloroquine	Methadone	Sulindac
Chlorothiazide	Methoxyphenamine	Temazepam
Chlorpheniramine	(+/-)- Methylenedioxyamphetamine (MDA)	11-Nor-Δ9- Tetrahydrocannabinol
Chlorpromazine	Methylphenidate	Tetracycline
Cholesterol	Nalbuphine	Tetrahydrozoline
Clomipramine	Nalidixic acid	Thiamine
Clonidine hydrochloride	Naloxone hydrochloride	L-Thyroxine
Cortisone	Naltrexone hydrochloride	ThioridazineHydrochloride
Cotinine(-)	Naproxen	Triamterene
Creatinine	Niacinamide	Triflupromazine Hydrochloride

Deoxyepinephrine	Nifedipine	Trimethoprim
Dextromethorphan	Norethindrone	Trimipramine
Diazepam	Noscapine	Tryptamine
Diflunisal	Oxazepam	DL-Tryptophan
Digoxin	Oxymetazoline	Tyramine
Doxylamine	Papaverine	D/L-Tyrosine
Ecgonine methylester	Penicillin	Uric Acid
R(-)-Epinephrine	Pentobarbital	Verapamil
Erythromycin	Perphenazine	Zomepirac
Estrone-3-sulfate	Phencyclidine	

Nortriptyline

Acetophenetidin	Ethyl-p-aminobenzoate	Phencyclidine
N-Acetylprocainamide	Fenoprofen	Phenelzine
Acetylsalicylic Acid (Aspirin)	Furosemide	Phenobarbital
Aminopyrine	Gentisic acid	Phentermine
Amoxicillin	Hemoglobin	Phenylephrine-L
Amobarbital	Hydralazine	Phenylethylamine
D-Amphetamine	(+/-)-4-Hydroxyamphetamine HCL	Phenylpropanolamine
L-Amphetamine	Hydrochlorothiazide	Prednisolone Acetate
Amphetamine Sulfate	Hydrocodone	Prednisone
Ampicillin(Ampicillin)	Hydrocortisone	Procaine(Novocaine)
Apomorphine	a -Hydroxyhippuric acid	Propoxyphene,d-
L-Ascorbic Acid	p-Hydroxymethamphetamine	Propranolol
Aspartame	Ibuprofen	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	Meprobamate	Sulfamethazine
Chlordiazepoxide HCL	Methadone	Sulindac
Chloroquine	Methoxyphenamine	Temazepam
Chlorothiazide	(+/-)- Methylenedioxyamphetamine (MDA)	11-Nor-Δ9- Tetrahydrocannabinol
Chlorpheniramine	Methylphenidate	Tetracycline

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

EDDP

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

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

Propoxyphene (Cut-off=300 ng/mL)	Result	% Cross-Reactivity
Propoxyphene	Positive at 300 ng/mL	100%
Norpropoxyphene	Positive at 300 ng/mL	100%

Nortriptyline (Cut-off=1000 ng/mL)	Result	% Cross- Reactivity
Nortriptyline	Positive at 1000 ng/mL	100%
Amitriptyline	Positive at 1500 ng/mL	67%
Clomipramine	Positive at 50000 ng/mL	2%
Desipramine	Positive at 5000 ng/mL	20%
Doxepine	Positive at 10000 ng/mL	10%
Imipramine	Positive at 10000 ng/mL	10%
Maprotiline	Positive at 100000 ng/mL	1%
Nordoxepin	Positive at 10000 ng/mL	10%
Promazine	Positive at 50000 ng/mL	2%
Promethazine	Positive at 2500 ng/mL	40%
Trimipramine	Positive at 50000 ng/mL	2%
Cyclobenzaprine Hydrochloride	Positive at 5000 ng/mL	20%
Norclomipramine	Positive at 50000 ng/mL	2%

EDDP (Cut-off=300 ng/mL)	Result	% Cross- Reactivity
EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	Positive at 300 ng/mL	100%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	Positive at 500 ng/mL	60%
Disopyramide	Positive at 50000 ng/mL	1%
Methadone	Negative at 100000	<0.3
LAAM (Levo-alpha-acetylmethadol) HCl	Negative at 100000	<0.3
Alpha Methadol	Negative at 100000	<0.3
Doxylamine	Negative at 100000	<0.3

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 Propoxyphene Test, the Nortriptyline Test and the EDDP 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:

Propoxyphene

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	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 Propoxyphene Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	PPX67	301	Negative
Viewer A	PPX66	304	Negative
Viewer B	PPX67	301	Negative
Viewer C	PPX67	301	Negative
Viewer C	PPX66	304	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	14	24
	Negative	10	15	15	2	0

Discordant Results of Propoxyphene Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	PPX67	301	Negative
Viewer A	PPX66	304	Negative
Viewer B	PPX67	301	Negative
Viewer C	PPX67	301	Negative
Viewer C	PPX66	304	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	14	24
	Negative	10	15	15	2	0

Discordant Results of Propoxyphene Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	PPX67	301	Negative
Viewer A	PPX66	304	Negative
Viewer B	PPX67	301	Negative
Viewer B	PPX66	304	Negative
Viewer C	PPX67	301	Negative
Viewer C	PPX66	304	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 Propoxyphene Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	PPX67	301	Negative
Viewer A	PPX66	304	Negative
Viewer B	PPX67	301	Negative
Viewer B	PPX66	304	Negative
Viewer C	PPX67	301	Negative
Viewer C	PPX66	304	Negative

Nortriptyline

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	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 Nortriptyline Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	TCA27	1011	Negative
Viewer B	TCA51	1025	Negative
Viewer B	TCA27	1011	Negative
Viewer C	TCA51	1025	Negative
Viewer C	TCA27	1011	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	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Nortriptyline Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	TCA51	1025	Negative
Viewer A	TCA34	1232	Negative
Viewer A	TCA52	1123	Negative
Viewer B	TCA51	1025	Negative
Viewer B	TCA34	1232	Negative
Viewer C	TCA51	1025	Negative
Viewer C	TCA34	1232	Negative
Viewer C	TCA52	1123	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 Nortriptyline Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	TCA51	1025	Negative
Viewer A	TCA27	1011	Negative
Viewer B	TCA51	1025	Negative
Viewer B	TCA27	1011	Negative
Viewer C	TCA51	1025	Negative
Viewer C	TCA27	1011	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 Nortriptyline Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	TCA51	1025	Negative
Viewer A	TCA27	1011	Negative
Viewer A	TCA38	1097	Negative
Viewer B	TCA51	1025	Negative
Viewer B	TCA27	1011	Negative
Viewer B	TCA38	1097	Negative
Viewer C	TCA51	1025	Negative
Viewer C	TCA27	1011	Negative
Viewer C	TCA38	1097	Negative

EDDP

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	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of EDDP Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	EDDP28	308	Negative
Viewer A	EDDP02	302	Negative
Viewer A	EDDP72	303	Negative
Viewer B	EDDP02	302	Negative
Viewer B	EDDP72	303	Negative
Viewer C	EDDP28	308	Negative
Viewer C	EDDP02	302	Negative
Viewer C	EDDP72	303	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	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 EDDP Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	EDDP28	308	Negative
Viewer A	EDDP02	302	Negative
Viewer A	EDDP72	303	Negative
Viewer B	EDDP02	302	Negative
Viewer B	EDDP72	303	Negative
Viewer C	EDDP02	302	Negative

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer C	EDDP72	303	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	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 EDDP Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	EDDP02	302	Negative
Viewer A	EDDP72	303	Negative
Viewer B	EDDP28	308	Negative
Viewer B	EDDP02	302	Negative
Viewer B	EDDP72	303	Negative
Viewer C	EDDP02	302	Negative
Viewer C	EDDP72	303	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	14	24
	Negative	10	15	15	2	0

Discordant Results of EDDP Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	EDDP02	302	Negative
Viewer A	EDDP72	303	Negative
Viewer B	EDDP02	302	Negative
Viewer B	EDDP72	303	Negative
Viewer C	EDDP02	302	Negative
Viewer C	EDDP72	303	Negative

Lay-user study

A lay user study was performed at three intended user sites with 560 lay persons testing each of the Propoxyphene, the Nortriptyline and the EDDP devices. Total of 1680 individuals performed the study. A total of 204 females and 356 males tested the Propoxyphene samples, 213 females and 347 males tested the Nortriptyline samples and 209 females and 351 males tested the EDDP 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 (Propoxyphene Strip)

% of Cutoff	Number of samples	Propoxyphene 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	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	18	2	90%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

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

% of Cutoff	Number of samples	Propoxyphene 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	75	0	20	100%

-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	2	18	90%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

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

% of Cutoff	Number of samples	Propoxyphene 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	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	18	2	90%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

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

% of Cutoff	Number of samples	Propoxyphene 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	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

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

% of Cutoff	Number of samples	Nortriptyline 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	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	2	18	90%

+25% Cutoff	20	1250	18	2	90%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

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

% of Cutoff	Number of samples	Nortriptyline 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	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	1	19	95%
+25% Cutoff	20	1250	19	1	95%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

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

% of Cutoff	Number of samples	Nortriptyline 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	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	2	18	90%
+25% Cutoff	20	1250	18	2	90%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

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

% of Cutoff	Number of samples	Nortriptyline 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	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	2	18	90%
+25% Cutoff	20	1250	18	2	90%

+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

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

% of Cutoff	Number of samples	EDDP 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	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	2	18	90%
+25% Cutoff	20	375	18	2	90%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

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

% of Cutoff	Number of samples	EDDP 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	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	2	18	90%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

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

% of Cutoff	Number of samples	EDDP 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	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%

+75% Cutoff	20	525	20	0	100%
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Comparison between GC/MS and Lay Person Results (EDDP Cup)

% of Cutoff	Number of samples	EDDP 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	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	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 Propoxyphene Test, Healgen Nortriptyline Test and Healgen EDDP (Methadone Metabolite) Test are substantially equivalent to the predicate.