



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

April 24, 2015

Re: K150791

Trade/Device Name: Healgen Secobarbital Test (Strip, Cassette, Cup, Dip Card),
Healgen Buprenorphine Test (Strip, Cassette, Cup, Dip Card),
Healgen Methadone Test (Strip, Cassette, Cup, Dip Card)

Regulation Number: 21 CFR 862.3150

Regulation Name: Barbiturate test system

Regulatory Class: II

Product Code: DIS, DJR, DJG

Dated: March 15, 2015

Received: March 25, 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 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 -S

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

Indications for Use

510(k) Number (if known)

k150791

Device Name

Healgen Secobarbital Test (Strip, Cassette, Cup, Dip Card)
Healgen Buprenorphine Test (Strip, Cassette, Cup, Dip Card)
Healgen Methadone Test (Strip, Cassette, Cup, Dip Card)

Indications for Use (Describe)

Healgen Secobarbital Test is an immunochromatographic assay for the qualitative determination of Secobarbital 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 Secobarbital 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 Secobarbital 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 Buprenorphine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a Cut-Off concentration of 10 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 Buprenorphine 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 Buprenorphine 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 Methadone Test is an immunochromatographic assay for the qualitative determination of Methadone 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: April 21, 2015
2. Submitter: HEALGEN SCIENTIFIC LLC
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4. Device Name: Healgen Secobarbital Test (Strip, Cassette, Cup, Dip Card)
Healgen Buprenorphine Test (Strip, Cassette, Cup, Dip Card)
Healgen Methadone Test (Strip, Cassette, Cup, Dip Card)

Classification:

Product Code	CFR #	Panel
DIS	21 CFR, 862.3150 Barbiturate Test System	Toxicology
DJR	21 CFR, 862.3620 Methadone Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

5. Predicate Devices:
k132812
UCP Multi-Drug Test Key Cups
6. Intended Use / Indications for Use
Healgen Secobarbital Test is an immunochromatographic assay for the qualitative determination of Secobarbital 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 Secobarbital 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 Secobarbital 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 Buprenorphine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a Cut-Off concentration of 10 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 Buprenorphine 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 Buprenorphine 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 Methadone Test is an immunochromatographic assay for the qualitative determination of Methadone 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 Secobarbital Test, Healgen Buprenorphine Test and Healgen Methadone Test are immunochromatographic assays for Secobarbital, Buprenorphine and Methadone. Each assay test is a lateral flow system for the qualitative detection of Secobarbital, Buprenorphine and Methadone (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 Secobarbital Test, Healgen Buprenorphine Test and Healgen Methadone Test and the predicate device is provided in Table 1, Table 2 and Table 3.

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

Item	Device	Predicate – K132812
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Secobarbital	the class of barbiturates including secobarbital
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 Buprenorphine Test and the Predicate Device

Item	Device	Predicate – K132812
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Buprenorphine	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	10 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 Methadone Test and the Predicate Device

Item	Device	Predicate – K132812
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Methadone	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 Secobarbital Test, Healgen Buprenorphine Test and Healgen Methadone Test are rapid tests for the qualitative detection of Secobarbital, Buprenorphine and Methadone 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:

Secobarbital
Strip Format

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								
Lot: BAR1201001	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201002	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201003	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								
Lot: BAR1201004	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201005	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201006	50-/0+	50-/0+	50-/0+	50-/0+	17-/33+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								
Lot: BAR1201007	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201008	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201009	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								
Lot: BAR1201010	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201011	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BAR1201012	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Buprenorphine

Strip Format

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								
Lot: BUP1204001	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204002	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204003	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	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: BUP1204004	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204005	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204006	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	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: BUP1204007	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204008	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204009	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	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: BUP1204010	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204011	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: BUP1204012	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Methadone

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: MTD1202001	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MTD1202002	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MTD1202003	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	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: MTD1202004	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MTD1202005	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MTD1202006	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	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: MTD1202007	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MTD1202008	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								
Lot: MTD1202009	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Result	-100%	-75%	-50%	-25%	Cut-off	+25%	+50%	+75%	+100%
Drug	Cut-off								
Lot: MTD1202010	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MTD1202011	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: MTD1202012	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	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 Secobarbital, Buprenorphine and Methadone. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Secobarbital Test	Secobarbital	300
Buprenorphine Test	Buprenorphine	10
Methadone Test	Methadone	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.

Secobarbital

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

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

Buprenorphine

Acetophenetidin	Ethyl-p-aminobenzoate	Phencyclidine
N-Acetylprocainamide	Fenoprofen	Phenelzine
Acetylsalicylic Acid (Aspirin)	Furosemide	Phenobarbital
Aminopyrine	Gentisic acid	Phterminate
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	(+/-)-Methylenedioxyampheta mine(MDA)	11-Nor-Δ9-Tetrahydrocannab inol

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	

Metadone

Acetophenetidin	Ethyl-p-aminobenzoate	Phenelzine
N-Acetylprocainamide	Fenoprofen	Phenobarbital
Acetylsalicylic Acid (Aspirin)	Furosemide	Pentermine
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
Ampicillin(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	Methoxyphenamine	Temazepam
Chlorothiazide	(+/-)-Methylenedioxyampheta mine(MDA)	11-Nor- Δ 9-Tetrahydrocannab inol
Chlorpheniramine	Methylphenidate	Tetracycline
Chlorpromazine	Nalbuphine	Tetrahydrozoline
Cholesterol	Nalidixic acid	Thiamine
Clomipramine	Naloxone hydrochloride	L-Thyroxine
Clonidine hydrochloride	Naltrexone hydrochloride	ThioridazineHydrochloride
Cortisone	Naproxen	Triamterene
Cotinine(-)	Niacinamide	Triflupromazine Hydrochloride
Creatinine	Nifedipine	Trimethoprim
Deoxyepinephrine	Norethindrone	Trimipramine
Dextromethorphan	Norpropoxyphene	Tryptamine
Diazepam	Noscapine	DL-Tryptophan
Diffunisal	Oxazepam	Tyramine
Digoxin	Oxymetazoline	D/L-Tyrosine
Doxylamine	Papaverine	Uric Acid
Ecgonine methylester	Penicillin	Verapamil
R(-)-Epinephrine	Pentobarbital	Zomepirac
Erythromycin	Perphenazine	
Estrone-3-sulfate	Phencyclidine	

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.

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

Alphenol	Positive at 750 ng/mL	40%
Aprobarbital	Positive at 250 ng/mL	120%
Butabarbital	Positive at 2500 ng/mL	12%
Butathal	Positive at 2500 ng/mL	12%
Butalbital	Positive at 2500ng/mL	12%
Cyclopentobarbital	Positive at 500 ng/mL	60%
Pentobarbital	Positive at 2500 ng/mL	12%
Phenobarbital	Positive at 25000 ng/mL	1%

Buprenorphine (Cut-off=10 ng/mL)	Result	% Cross-Reactivity
Buprenorphine	Positive at 10 ng/mL	100%
Buprenorphine -3-D-Glucuronide	Positive at 10 ng/mL	100%
Norbuprenorphine	Positive at 20 ng/mL	50%
Norbuprenorphine -3-D-Glucuronide	Positive at 20 ng/mL	50%
Morphine	Negative at 100000	Not detected
Oxymorphone	Negative at 100000	Not detected
Hydromorphone	Negative at 100000	Not detected

Methadone (Cut-off=300 ng/mL)	Result	% Cross-Reactivity
Methadone	Positive at 300 ng/mL	100%
Doxylamine	Positive at 5000 ng/mL	6%
EDDP	Negative at 100000	Not detected
EMDP	Negative at 100000	Not detected
LAAM HCl	Negative at 100000	Not detected
Alpha Methadol	Negative at 100000	Not detected

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 Secobarbital Test, the Buprenorphine Test and the Methadone 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:

Secobarbital

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 Secobarbital Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	BAR06	303	Negative
Viewer A	BAR72	302	Negative
Viewer B	BAR06	303	Negative
Viewer B	BAR72	302	Negative
Viewer C	BAR06	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	13	24
	Negative	10	15	15	3	0

Discordant Results of Secobarbital Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	BAR06	303	Negative
Viewer A	BAR16	308	Negative
Viewer A	BAR72	302	Negative
Viewer B	BAR06	303	Negative
Viewer B	BAR72	302	Negative
Viewer C	BAR72	302	Negative
Viewer C	BAR06	303	Negative
Viewer C	BAR16	308	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	14	24
	Negative	10	15	15	2	0

Discordant Results of Secobarbital Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	BAR06	303	Negative
Viewer A	BAR16	308	Negative
Viewer A	BAR72	302	Negative
Viewer B	BAR06	303	Negative
Viewer B	BAR16	308	Negative
Viewer B	BAR72	302	Negative
Viewer C	BAR06	303	Negative
Viewer C	BAR72	302	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	13	24
	Negative	10	15	15	3	0

Discordant Results of Secobarbital Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	BAR06	303	Negative
Viewer A	BAR16	308	Negative
Viewer A	BAR72	302	Negative
Viewer B	BAR06	303	Negative
Viewer B	BAR16	308	Negative
Viewer B	BAR72	302	Negative
Viewer C	BAR06	303	Negative
Viewer C	BAR16	308	Negative
Viewer C	BAR72	302	Negative

Buprenorphine

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	14	24
	Negative	10	15	15	2	0

Discordant Results of Buprenorphine Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	BUP23	10.2	Negative
Viewer A	BUP67	10.6	Negative
Viewer A	BUP12	10.4	Negative
Viewer B	BUP23	10.2	Negative
Viewer B	BUP67	10.6	Negative
Viewer B	BUP12	10.4	Negative
Viewer C	BUP23	10.2	Negative
Viewer C	BUP12	10.4	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	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 Buprenorphine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	BUP23	10.2	Negative
Viewer A	BUP12	10.4	Negative
Viewer B	BUP23	10.2	Negative
Viewer B	BUP12	10.4	Negative
Viewer C	BUP23	10.2	Negative
Viewer C	BUP12	10.4	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	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 Buprenorphine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	BUP23	10.2	Negative
Viewer A	BUP67	10.6	Negative
Viewer A	BUP12	10.4	Negative
Viewer B	BUP23	10.2	Negative
Viewer B	BUP12	10.4	Negative
Viewer C	BUP23	10.2	Negative
Viewer C	BUP67	10.6	Negative
Viewer C	BUP12	10.4	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	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 Buprenorphine Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	BUP23	10.2	Negative
Viewer A	BUP67	10.6	Negative
Viewer A	BUP12	10.4	Negative
Viewer B	BUP23	10.2	Negative
Viewer B	BUP12	10.4	Negative
Viewer C	BUP23	10.2	Negative
Viewer C	BUP12	10.4	Negative

Methadone

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	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 Methadone Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	MTD80	302	Negative
Viewer A	MTD67	303	Negative
Viewer B	MTD80	302	Negative
Viewer B	MTD67	303	Negative
Viewer B	MTD59	306	Negative
Viewer C	MTD80	302	Negative
Viewer C	MTD67	303	Negative
Viewer C	MTD59	306	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	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 Methadone Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	MTD80	302	Negative
Viewer A	MTD67	303	Negative
Viewer B	MTD80	302	Negative
Viewer B	MTD67	303	Negative
Viewer C	MTD80	302	Negative
Viewer C	MTD67	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	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 Methadone Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	MTD80	302	Negative
Viewer A	MTD67	303	Negative
Viewer B	MTD80	302	Negative
Viewer B	MTD67	303	Negative
Viewer C	MTD80	302	Negative
Viewer C	MTD67	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	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 Methadone Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	MTD80	302	Negative
Viewer A	MTD67	303	Negative
Viewer A	MTD59	306	Negative
Viewer B	MTD80	302	Negative
Viewer B	MTD67	303	Negative
Viewer C	MTD80	302	Negative
Viewer C	MTD67	303	Negative

Lay-user study

A lay user study was performed at three intended user sites with 560 lay persons testing each of the Secobarbital, the Buprenorphine and the Methadone devices. Total of 1680 individuals performed the study. A total of 190 females and 370 males tested the Secobarbital samples, 217 females and 343 males tested the Buprenorphine samples and 216 females and 344 males tested the Methadone 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 (Secobarbital Strip)

% of Cutoff	Number of samples	Secobarbital 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 (Secobarbital Cassette)

% of Cutoff	Number of samples	Secobarbital 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 (Secobarbital DipCard)

% of Cutoff	Number of samples	Secobarbital 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 (Secobarbital Cup)

% of Cutoff	Number of samples	Secobarbital 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 (Buprenorphine Strip)

% of Cutoff	Number	Buprenorphine	Lay person results	The
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	of samples	Concentration by GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	2.5	0	20	100%
-50% Cutoff	20	5	0	20	100%
-25% Cutoff	20	7.5	1	19	95%
+25% Cutoff	20	12.5	18	2	90%
+50% Cutoff	20	15	20	0	100%
+75% Cutoff	20	17.5	20	0	100%

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

% of Cutoff	Number of samples	Buprenorphine 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	2.5	0	20	100%
-50% Cutoff	20	5	0	20	100%
-25% Cutoff	20	7.5	1	19	95%
+25% Cutoff	20	12.5	19	1	95%
+50% Cutoff	20	15	20	0	100%
+75% Cutoff	20	17.5	20	0	100%

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

% of Cutoff	Number of samples	Buprenorphine 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	2.5	0	20	100%
-50% Cutoff	20	5	0	20	100%
-25% Cutoff	20	7.5	2	18	90%
+25% Cutoff	20	12.5	18	2	90%
+50% Cutoff	20	15	20	0	100%
+75% Cutoff	20	17.5	20	0	100%

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

% of Cutoff	Number	Buprenorphine	Lay person results	The
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	of samples	Concentration by GC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	2.5	0	20	100%
-50% Cutoff	20	5	0	20	100%
-25% Cutoff	20	7.5	2	18	90%
+25% Cutoff	20	12.5	18	2	90%
+50% Cutoff	20	15	20	0	100%
+75% Cutoff	20	17.5	20	0	100%

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

% of Cutoff	Number of samples	Methadone 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 (Methadone Cassette)

% of Cutoff	Number of samples	Methadone 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 (Methadone DipCard)

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

% of Cutoff	Number of samples	Methadone 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%

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 Secobarbital Test, Healgen Buprenorphine Test and Healgen Methadone Test are substantially equivalent to the predicate.