



August 20, 2018

Safecare Biotech (Hangzhou) Co.,Ltd.
% Joe Shia, Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K181968

Trade/Device Name: SAFECARE Multi-Drug Urine Test Cup
SAFECARE Multi-Drug Urine Test DipCard

Regulation Number: 21 CFR 862.3100

Regulation Name: Amphetamine test system

Regulatory Class: Class II

Product Code: NFT, NFW, NFY, NGG, NGL, NFV, PTH, PTG

Dated: July 18, 2018

Received: July 24, 2018

Dear 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 Part

801 and Part 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Kellie B. Kelm -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)

k181698

Device Name

SAFECARE® Multi-Drug Urine Test Dip Card

SAFECARE® Multi-Drug Urine Test Cup

Indications for Use (Describe)

SAFECARE® Multi-Drug Urine Test Dip Card is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital and Methadone in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	2000 ng/mL
Secobarbital	300 ng/mL
Methadone	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam and Secobarbital when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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 or LC/MS is the preferred confirmatory method.

The tests are intended for over-the-counter use.

SAFECARE® Multi-Drug Urine Test Cup is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital and Methadone in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	2000 ng/mL
Secobarbital	300 ng/mL
Methadone	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam and Secobarbital when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration

and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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 or LC/MS is the preferred confirmatory method. The tests are intended 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 k181968

1. Date: August 17, 2018
2. Submitter: Safecare Biotech (Hangzhou) Co. Ltd.
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4. Device Name: SAFECARE Multi-Drug Urine Test Dip Card
SAFECARE Multi-Drug Urine Test Cup

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine Test System	Toxicology (91)
NGG Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGL Morphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
PTG Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)

5. Predicate Devices: K142396

The Chemtrue® Multi-Panel Drug Screen Dip Card Tests

6. Intended Use

SAFECARE® Multi-Drug Urine Test Dip Card is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital and Methadone in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL

Methamphetamine	1000 ng/mL
Morphine	2000 ng/mL
Secobarbital	300 ng/mL
Methadone	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam and Secobarbital when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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 or LC/MS is the preferred confirmatory method. The tests are intended for over-the-counter use.

SAFECARE® Multi-Drug Urine Test Cup is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital and Methadone in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	2000 ng/mL
Secobarbital	300 ng/mL
Methadone	300 ng/mL

Configuration of SAFECARE® Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Oxazepam and Secobarbital when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. 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 or LC/MS is the preferred confirmatory method. The tests are intended for over-the-counter use.

7. Device Description

The SAFECARE Dip Card Tests and SAFECARE Cup Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Secobarbital and Methadone (target analytes) in human urine. The products are single-use in vitro diagnostic devices, which come in the formats of Dip Cards or Cups. Each test kit contains a Test Device (in one of the two formats), a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the SAFECARE Dip Card Tests and SAFECARE Cup Tests and the predicate devices is provided in following tables.

Table 1: Features Comparison of SAFECARE Dip Card Tests and the Predicate Devices

Item	Device	Predicate - K142396
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (OPI): 2000ng/mL Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Dip Card	Dip Card

Table 2: Features Comparison of SAFECARE Cup Tests and the Predicate Devices

Item	Device	Predicate - K142396
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (OPI): 2000ng/mL Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml	Same

Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Cup	Dip Card

9. Test Principle

The SAFECARE Dip Card Tests, and SAFECARE Cup Tests are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Secobarbital and Methadone in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific 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 cutoff-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 tests have 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, 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 LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following tables for Secobarbital, Oxazepam, Methamphetamine, Methadone and Morphine. The rest data were reported in k153646 for Amphetamine, Marijuana and Cocaine.

Secobarbital Dip Card

Lot Number	Results									
	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%	
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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-	

Lot Number \ Results	Results									
	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%	
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-	

Cup

Lot Number \ Results	Results									
	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%	
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+	25-/25+	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-	

Oxazepam

Dip Card

Lot Number \ Results	Results									
	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%	
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+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-	
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-	

Cup

Lot Number \ Results	Results									
	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%	
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+	24-/26+	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-	

Methamphetamine

Dip Card

Lot Number \ Results	Results									
	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%	
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+	24-/26+	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-	

Cup

Lot Number \ Results	Results									
	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%	
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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-	
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-	

Methadone

Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	24-/26+	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-

Morphine

Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

The following cut-off values are verified.

Drug(Identifier)	Cut-off level
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methadone (MTD)	300 ng/mL
Morphine (OPI)	2000 ng/mL

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 50 °C and real time stability studies at 4°C and 30 °C.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables. There were no differences observed between the SAFECARE Cup and Dip Card formats.

Acetaminophen (4-Acetamidophenol)	Ecgonine methyl ester	D,L-Octopamine
Acetophenetidin	EMDP	Oxalic acid
N-Acetylprocainamide	Erythromycin	Oxolinic acid
Acetylsalicylic acid	β-Estradiol	Oxymetazoline
Albumin	Fenoprofen	Papaverine
Aminopyrine	Furosemide	Penicillin-G
Amoxicillin	Gentisic acid	Perphenazine
Ampicillin	Hemoglobin	Phenelzine
Apomorphine	Hydralazine	Prednisone
Ascorbic acid	Hydrochlorothiazide	DL-Propranolol
Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinine
Benzilic acid	3-Hydroxytyramine	Ranitidine
Benzoic acid	Ibuprofen	Salicylic acid
Bilirubin	D,L-Isoproterenol	Serotonin (5- Hydroxytyramine)
Chloralhydrate	Isoxsuprine	Sulfamethazine
Chloramphenicol	Ketamine	Sulindac
Chlorothiazide	Ketoprofen	Tetrahydrocortisone, 3-acetate
Chlorpromazine	Labetalol	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Loperamide	Tetrahydrozoline
Clonidine	Maprotiline	Thiamine
Cortisone	Meperidine	Thioridazine
(-) Cotinine	Meprobamate	Triamterene
Creatinine	Methoxyphenamine	DL-Tyrosine
Deoxycorticosterone	Nalidixic acid	Trifluoperazine
Dextromethorphan	Naloxone	Trimethoprim
Diclofenac	Naltrexone	D L-Tryptophan
Diflunisal	Naproxen	Tyramine
Digoxin	Niacinamide	Uric acid
Diphenhydramine	Nifedipine	Verapamil
Disopyramide	Norethindrone	Zomepirac
EDDP	Noscapine	

e. Specificity

To test specificity, drug metabolites and other structure related compounds that are likely to cross-react in urine samples were tested using three batches of each device. The lowest concentration that caused a positive result for each compound are listed below

for Secobarbital, Oxazepam, Methamphetamine, Methadone and Morphine. The rest data were reported in k153646 for Amphetamine, Marijuana and Cocaine. There were no differences observed between the SAFECARE Cup and Dip Card formats.

Secobarbital (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Secobarbital	300	100%
Amobarbital	625	48%
Alphenol	625	48%
Aprobarbital	200	150%
Butobarbital	100	300%
Butathal	200	150%
Butalbital	2500	12%
Cyclopentobarbital	400	75%
Pentobarbital	1000	30%
Phenobarbital	300	100%

Oxazepam (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Oxazepam	300	100%
Alprazolam	250	120%
a-Hydroxyalprazolam	1000	30 %
Bromazepam	625	48 %
Chlordiazepoxide	2500	12 %
Clonazepam	2500	12 %
Clobazam	125	240 %
Clorazepate dipotassium	100	300 %
Desalkylflurazepam	250	120 %
Diazepam	250	120 %
Estazolam	5000	6%
Flunitrazepam	375	80 %
D,L-Lorazepam	10000	3 %
Midazolam	90000	0.33%
Nitrazepam	25000	1.2%
Norchlordiazepoxide	250	120%
Nordiazepam	500	60%
Temazepam	125	240%
Triazolam	5000	6%

Methamphetamine (Cut-off=1000 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
D(+)-Methamphetamine	1000	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	50000	2%
D/L-Methamphetamine	1000	100%
p-Hydroxymethamphetamine	10000	10%
D-Amphetamine	Negative at 100000	≤1%
L-Amphetamine	Negative at 100000	≤1%
Chloroquine	25000	4 %
(+/-)-Ephedrine	4000	25%
L-Methamphetamine	10000	10 %
(+/-)3,4-Methylenedioxymphetamine (MDA)	Negative at 100000	≤1%
β -Phenylethylamine	7500	13%
Trimethobenzamide	20000	5%
(+/-)3,4-methylenedioxyamphetamine	2000	50%

(MDMA)		
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Methadone (Cut-off=300 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Methadone	300	100%
Doxylamine	5000	6%
LAAM HCl	10000	3%
Alpha Methadol	2000	15%
EDDP	>100000	<0.3%
EMDP	>100000	<0.3%

Morphine (Cut-off=2000 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Morphine	2000	100 %
Acetylmorphine	2500	80 %
Codeine	2000	100 %
Ethyl Morphine	600	333 %
Heroin	2000	100%
Hydromorphone	15000	13%
Hydrocodone	15000	13%
Thebaine	20000	10%
Morphine-3-β-d-glucuronide	10000	20%
Procaine	Negative at 400000	≤0.5%
Levorphanol	Negative at 400000	≤0.5%
Oxycodone	20000	10%
Oxymorphone	20000	10%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 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 lots of each device. 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 between the SAFECARE Cup and Dip Card formats.

2. Comparison Studies

Method comparison studies for the SAFECARE Dip Card Tests and the SAFECARE Cup Tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for Secobarbital, Oxazepam, Methamphetamine, Methadone and Morphine. The rest data were reported in k153646 for Amphetamine, Marijuana and Cocaine.

Secobarbital

Dip Card	Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)

Viewer A	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer B	Positive	0	0	2	20	20
	Negative	10	10	18	0	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	10	19	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	SM8315	289	Positive
Viewer B	SM8315	289	Positive
Viewer B	SM2505	235	Positive
Viewer C	SM5420	249	Positive

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	20	20
	Negative	10	10	18	0	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	10	19	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	SM5080	289	Positive
Viewer A	SM9194	249	Positive
Viewer B	SM5080	289	Positive
Viewer C	SM9194	249	Positive

Oxazepam

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	20
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	19	20
	Negative	10	10	18	1	0

Viewer C	Positive	0	0	2	20	20
	Negative	10	10	19	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	SM9014	236	Positive
Viewer A	SM6306	288	Positive
Viewer B	SM7026	245	Positive
Viewer C	SM9014	236	Positive
Viewer C	SM7026	245	Positive
Viewer A	SM6235	367	Negative
Viewer B	SM6235	367	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	20
	Negative	10	10	18	1	0
Viewer B	Positive	0	0	2	19	20
	Negative	10	10	18	1	0
Viewer C	Positive	0	0	1	19	20
	Negative	10	10	19	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	SM1575	236	Positive
Viewer A	SM3552	288	Positive
Viewer B	SM3552	288	Positive
Viewer B	SM5707	245	Positive
Viewer C	SM3552	288	Positive
Viewer A	SM3141	367	Negative
Viewer B	SM3141	367	Negative
Viewer C	SM3141	367	Negative

Methamphetamine

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	20	20
	Negative	10	10	20	0	0

Viewer B	Positive	0	0	0	19	20
	Negative	10	10	20	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	10	20	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	SM5938	1279	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	19	20
	Negative	10	10	20	1	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	10	20	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	10	20	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	SM7866	1279	Negative

Methodone

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	19	20
	Negative	10	10	19	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	10	20	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	SM7688	238	Positive
Viewer B	SM5599	246	Positive
Viewer A	SM4407	361	Negative

Viewer B	SM6683	372	Negative
Viewer C	SM4407	361	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Viewer C	Positive	0	0	2	18	20
	Negative	10	10	18	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	SM0442	246	Positive
Viewer B	SM3857	238	Positive
Viewer C	SM0442	246	Positive
Viewer C	SM8431	228	Positive
Viewer A	SM3805	372	Negative
Viewer C	SM3805	372	Negative
Viewer C	SM5346	361	Negative

Morphine

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	2	18	20
	Negative	10	10	18	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	SM1232	1994	Positive
Viewer B	SM8496	1928	Positive
Viewer C	SM8496	1928	Positive

Viewer C	SM1232	1994	Positive
Viewer A	SM8757	2049	Negative
Viewer B	SM4835	2184	Negative
Viewer B	SM9254	2100	Negative
Viewer C	SM8757	2049	Negative
Viewer C	SM9254	2100	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer B	Positive	0	0	0	18	20
	Negative	10	10	20	2	0
Viewer C	Positive	0	0	1	19	20
	Negative	10	10	19	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	SM3243	1994	Positive
Viewer C	SM3243	1994	Positive
Viewer A	SM5564	2049	Negative
Viewer A	SM8381	2184	Negative
Viewer B	SM5564	2049	Negative
Viewer B	SM9915	2100	Negative
Viewer C	SM8381	2184	Negative

Lay-user study

A lay user study was performed at three intended user sites with 240 lay persons for each device format. The lay users had diverse educational and professional backgrounds and ranged in age from 18 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 LC/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. Each device was tested. Results are shown below.

Dip Card

AMP

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	248	0	20	100

-50% Cutoff	100	505	0	100	100
-25% Cutoff	20	754	1	19	95
+25% Cutoff	20	1259	17	3	85
+50% Cutoff	40	1508	40	0	100
+75% Cutoff	20	1759	20	0	100

COC

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	74	0	20	100
-50% Cutoff	100	152	0	100	100
-25% Cutoff	20	224	2	18	90
+25% Cutoff	20	373	18	2	90
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	522	20	0	100

THC

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	12.6	0	20	100
-50% Cutoff	100	25	0	100	100
-25% Cutoff	20	37.2	2	18	90
+25% Cutoff	20	62.3	19	1	95
+50% Cutoff	40	75	40	0	100
+75% Cutoff	20	87.4	20	0	100

BAR

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76	0	20	100
-50% Cutoff	100	151	0	100	100
-25% Cutoff	20	226	1	19	95
+25% Cutoff	20	372	18	2	90
+50% Cutoff	40	448	40	0	100
+75% Cutoff	20	529	20	0	100

BZO

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		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	100	149	0	100	100
-25% Cutoff	20	224	3	17	85
+25% Cutoff	20	376	19	1	95
+50% Cutoff	40	454	40	0	100
+75% Cutoff	20	520	20	0	100

MET

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	251	0	20	100
-50% Cutoff	100	502	0	100	100
-25% Cutoff	20	758	2	18	90
+25% Cutoff	20	1259	18	2	90
+50% Cutoff	40	1512	40	0	100
+75% Cutoff	20	1759	20	0	100

MTD

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	74	0	20	100
-50% Cutoff	100	151	0	100	100
-25% Cutoff	20	225	1	19	95
+25% Cutoff	20	376	18	2	90
+50% Cutoff	40	447	40	0	100
+75% Cutoff	20	522	20	0	100

OPI

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	505	0	20	100
-50% Cutoff	100	1009	0	100	100
-25% Cutoff	20	1510	1	19	95
+25% Cutoff	20	2511	18	2	90
+50% Cutoff	40	3031	40	0	100
+75% Cutoff	20	3521	20	0	100

Cup

AMP

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	248	0	20	100
-50% Cutoff	100	505	0	100	100
-25% Cutoff	20	754	2	18	90
+25% Cutoff	20	1259	18	2	90
+50% Cutoff	40	1508	40	0	100
+75% Cutoff	20	1759	20	0	100

COC

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	74	0	20	100
-50% Cutoff	100	152	0	100	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	373	18	2	90
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	522	20	0	100

THC

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	12.6	0	20	100
-50% Cutoff	100	25	0	100	100
-25% Cutoff	20	37.2	2	18	90
+25% Cutoff	20	62.3	19	1	95
+50% Cutoff	40	75	40	0	100
+75% Cutoff	20	87.4	20	0	100

BAR

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76	0	20	100
-50% Cutoff	100	151	0	100	100
-25% Cutoff	20	226	3	17	85
+25% Cutoff	20	372	19	1	95
+50% Cutoff	40	448	40	0	100

+75% Cutoff	20	529	20	0	100
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BZO

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		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	100	149	0	100	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	376	18	2	90
+50% Cutoff	40	454	40	0	100
+75% Cutoff	20	520	20	0	100

MET

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	251	0	20	100
-50% Cutoff	100	502	0	100	100
-25% Cutoff	20	758	3	17	85
+25% Cutoff	20	1259	19	1	95
+50% Cutoff	40	1512	40	0	100
+75% Cutoff	20	1759	20	0	100

MTD

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	74	0	20	100
-50% Cutoff	100	151	0	100	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	376	19	1	95
+50% Cutoff	40	447	40	0	100
+75% Cutoff	20	522	20	0	100

OPI

% of Cutoff	Number of samples	Drug Concentration by LC/MS (ng/mL)	Lay person Results		Percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	505	0	20	100
-50% Cutoff	100	1009	0	100	100
-25% Cutoff	20	1510	3	17	85

+25% Cutoff	20	2511	19	1	95
+50% Cutoff	40	3031	40	0	100
+75% Cutoff	20	3521	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, method comparison, and lay-user studies of the devices, it's concluded that the SAFECARE Dip Card Tests and SAFECARE Cup Tests are substantially equivalent to the predicate.