



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

March 18, 2016

SAFECARE BIOTECH  
C/O JOE SHIA  
LSI INTERNATIONAL  
504 E DIAMOND AVE, SUITE I  
GAITHERSBURG, MD, 20877

Re: K153646

Trade/Device Name: SAFECARE Urine Test Amphetamine (Cassette, Cup, DipCard),  
SAFECARE Urine Test Cocaine (Cassette, Cup, DipCard),  
SAFECARE Urine Test Marijuana (Cassette, Cup, DipCard)

Regulation Number: 21 CFR 862.3250

Regulation Name: Cocaine and Cocaine Metabolite Test System

Regulatory Class: Class II

Product Code: DIO, LAF, LDJ

Dated: December 15<sup>th</sup>, 2015

Received: December 21<sup>st</sup>, 2015

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Courtney H. Lias -S**

Courtney H. Lias, Ph.D.

Director

Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153646

### Device Name

SAFECARE Urine Test Amphetamine (Cassette, Cup, DipCard)

SAFECARE Urine Test Cocaine (Cassette, Cup, DipCard)

SAFECARE Urine Test Marijuana (Cassette, Cup, DipCard)

### Indications for Use (Describe)

SAFECARE Urine Test Amphetamine Cassette is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Amphetamine Cup is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Amphetamine DipCard is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine Cassette is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine Cup is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine DipCard is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana Cassette is a rapid test for the qualitative detection of Cannabinoids in human urine at

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a cutoff concentration of 50 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana Cup is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana DipCard is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

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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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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510(k) SUMMARY

- 1. Date: March 17, 2016
- 2. Submitter: Safecare Biotech Co. Ltd.  
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Hangzhou, China
- 3. Contact person: Alex Qiu  
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Hangzhou, China  
Telephone: 86 571-89712897  
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Email: alexqiu@safecare.com.cn
- 4. Device Name: SAFECARE Urine Test Amphetamine (Cassette, Cup, DipCard)  
SAFECARE Urine Test Cocaine (Cassette, Cup, DipCard)  
SAFECARE Urine Test Marijuana (Cassette, Cup, DipCard)

Classification: Class II

Product Code	CFR #	Panel
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoid Test System	Toxicology

- 5. Predicate Devices:  
K052115  
First Check Multi Drug Cup 12
- 6. Intended Use  
SAFECARE Urine Test Amphetamine Cassette is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.  
The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Amphetamine Cup is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Amphetamine DipCard is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine Cassette is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine Cup is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine DipCard is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana Cassette is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana Cup is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana DipCard is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide 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. The tests are intended for over-the-counter and for prescription use.

## 7. Device Description

SAFECARE Urine Test devices are immunochromatographic assays for cocaine, amphetamine and marijuana. Each assay test is a lateral flow, one step system for the qualitative detection of Benzoyllecgonine, or D-amphetamine or 11-nor- $\Delta^9$ -THC-9 COOH (target analyte) in human urine. The product is a single-use in vitro diagnostic device, which comes in the form of: DipCards, or Cups or Cassettes. It contains a Test Device (in one of the three formats), a package insert and a urine cup. Each test device is sealed with a desiccant in an aluminum pouch.

## 8. Substantial Equivalence Information

A summary comparison of features of the SAFECARE Urine Test and the predicate device is provided in Table 1, Table 2 & Table 3.

**Table 1: Features Comparison of SAFECARE Cocaine Test and the Predicate Device**

Item	Device	Predicate - K052115
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<b>Item</b>	<b>Device</b>	<b>Predicate - K052115</b>
<b>Indication(s) for Use</b>	For the qualitative determination of Benzoylcegonine in human urine.	Same
<b>Calibrator</b>	Benzoylcegonine	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Cut-Off Values</b>	300 ng/mL	Same
<b>Intended Population</b>	For over-the-counter and prescription uses.	For over-the-counter use.
<b>Configurations</b>	Cup, Dip Card, Cassette	Cup

**Table 2: Features Comparison of SAFECARE Amphetamine Test and the Predicate Device**

<b>Item</b>	<b>Device</b>	<b>Predicate - K052115</b>
<b>Indication(s) for Use</b>	For the qualitative determination of D-amphetamine in human urine.	Same
<b>Calibrator</b>	D-amphetamine	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Cut-Off Values</b>	1000 ng/mL	Same
<b>Intended Population</b>	For over-the-counter and prescription uses.	For over-the-counter use.
<b>Configurations</b>	Cup, Dip Card, Cassette	Cup

**Table 3: Features Comparison of SAFECARE Marijuana Test and the Predicate Device**

<b>Item</b>	<b>Device</b>	<b>Predicate - K052115</b>
<b>Indication(s)</b>	For the qualitative determination of	Same



<b>Item</b>	<b>Device</b>	<b>Predicate - K052115</b>
<b>for Use</b>	11-nor- $\Delta$ 9-THC-9 COOH in human urine.	
<b>Calibrator</b>	11-nor- $\Delta$ 9-THC-9 COOH	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Cut-Off Values</b>	50 ng/mL	Same
<b>Intended Population</b>	For over-the-counter and prescription uses.	For over-the-counter use.
<b>Configurations</b>	Cup, Dip Card, Cassette	Cup

## 9. Test Principle

SAFECARE Urine Tests are rapid tests for the qualitative detection of Benzoyllecgonine, or D-amphetamine or 11-nor- $\Delta$ 9-THC-9 COOH 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 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.

## 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 blinded labeled and randomized. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables:

#### **Amphetamine (AMP) Dip Card Format**

Drug \ Result	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	47-/3+	24-/26+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-

**Amphetamine (AMP) 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+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	47-/3+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-

**Amphetamine (AMP) Cassette Format**

Drug \ Result	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	47-/3+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48/2+	25-/25+	47+/3-	50+/0-	50+/0-	50+/0-

**Cocaine (COC) Dip Card Format**

Drug \ Result	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-

**COC 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+	48-/2+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-

**COC Cassette Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	47-/3+	31-/29+	48+/2-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	48-/2+	28-/22+	47+/3-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	47-/3+	28-/22+	49+/1-	50+/0-	50+/0-	50+/0-

**Marijuana (THC) Dip Card Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-

**THC Cup Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	47+/3-	50+/0-	50+/0-	50+/0-

**THC Cassette Format**

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
<b>Lot 2</b>	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
<b>Lot 3</b>	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	47+/3-	50+/0-	50+/0-	50+/0-

<b>Drug \ Result</b>	<b>-100% Cut-off</b>	<b>-75% Cut-off</b>	<b>-50% Cut-off</b>	<b>-25% Cut-off</b>	<b>Cut-off</b>	<b>+25% Cut-off</b>	<b>+50% Cut-off</b>	<b>+75% Cut-off</b>	<b>+100% Cut-off</b>
<b>Lot 1</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>48-/2+</b>	<b>25-/25+</b>	<b>48+/2-</b>	<b>50+/0-</b>	<b>50+/0-</b>	<b>50+/0-</b>
<b>Lot 2</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>47-/3+</b>	<b>26-/24+</b>	<b>49+/1-</b>	<b>50+/0-</b>	<b>50+/0-</b>	<b>50+/0-</b>
<b>Lot 3</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>50-/0+</b>	<b>49-/1+</b>	<b>25-/25+</b>	<b>47+/3-</b>	<b>50+/0-</b>	<b>50+/0-</b>	<b>50+/0-</b>

b. Linearity

Not applicable, these are visually read devices.

c. Stability

The devices are stable at 4-30°C (39-86°F) for 24 months based on the accelerated stability study at 50°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 +50% cut-off and all negative at and below -50% cut-off for Amphetamine, Cocaine and Marijuana. The following cut-off values for the test devices have been verified.

<b>Test</b>	<b>Calibrator</b>	<b>Cut-off (ng/mL)</b>
<b>One Step Amphetamine Test</b>	D-amphetamine	1000
<b>One Step Cocaine Test</b>	Benzoyllecgonine	300
<b>One Step Marijuana Test</b>	11-nor- $\Delta^9$ -THC-9 COOH	50

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.

**AMP**

4-Acetamidophenol	L-Ephedrine	Oxycodone
Acetophenetidin	(-) Y Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	$\beta$ -Estradiol	Penicillin-G
Aminopyrine	Estrone-3-sulfate	Pentazocaine
Amitriptyline	Ethyl-p-aminobenzoate	Pentobarbital
Amobarbital	Fenfluramine	Perphenazine
Amoxicillin	Fenoprofen	Phencyclidine
Ampicillin	Furosemide	Phenelzine
Ascorbic acid	Gentisic acid	Phenobarbital
Aspartame	Hemoglobin	Phetoin
Atropine	Hydralazine	L-Phenylephrine
Benzilic acid	Hydrochlorothiazide	Phenylpropanolamine
Benzoic acid	Hydrocodone	Prednisolone
Benzoylcegonine	Hydrocortisone	Prednisone
Bilirubin	O-Hydroxyhippuric acid	Procaine
Brompheniramine	3-Hydroxytyramine	Promazine
Caffeine	Ibuprofen	Promethazine
Cannabidiol	Imipramine	D,L-Propranolol
Cannabinol	(-) Isoproterenol	D-Propoxyphene
Chloralhydrate	Isoxsuprine	Quinidine
Chloramphenicol	Ketamine	Quinine
Chlordiazepoxide	Ketoprofen	Ranitidine
Chlorothiazide	Labetalol	Salicylic acid
( $\pm$ ) Chlorpheniramine	Levorphanol	Secobarbital
Chlorpromazine	Loperamide	Sulfamethazine
Chlorquine	Maprotiline	Sulindac
Cholesterol	Meperidine	Temazepam
Clomipramine	Meprobamate	Tetracycline
Clonidine	Methadone	Tetrahydrocortisone
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-Dglucuronide	$\Delta^9$ -THC-COOH
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	D,L-Thyroxine
Dextromethorphan	Niacinamide	Tolbutamine
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine

Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tyrosine
Ecgonine hydrochloride	Oxalic acid	Uric acid
Ecgonine methylester	Oxazepam	Verapamil
(1R,2S)-(-)-Ephedrine	Oxolinic acid	Zomepirac

## COC

Acetaminophen	Estrone-3-sulfate	Oxymetazoline
Acetophenetidin	Ethyl-p-aminobenzoate	Papaverine
N-Acetylprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylic acid	Furosemide	Pentobarbital
Aminopyrine	Gentisic acid	Perphenazine
Amitriptyline	Hemoglobin	Phencyclidine
Amobarbital	Hydralazine	Phenelzine
Amoxicillin	Hydrochlorothiazide	Phenobarbital
Ampicillin	Hydrocodone	Phentermine
L-Ascorbic acid	Hydrocortisone	L-Phenylephrine
DL-Amphetamine Sulfate	O-Hydroxyhippuric acid	$\beta$ -Phenylethylamine
Apomorphine	p-Hydroxymethamphetamine	Phenylpropanolamine
Aspartame	3-Hydroxytyramine	Prednisolone
Atropine	Ibuprofen	Prednisone
Benzilic acid	Imipramine	Procaine
Benzoic acid	Iproniazid	Promazine
Benzphetamine	( $\pm$ ) - Isoproterenol	Promethazine
( $\pm$ ) -Brompheniramine	Isoxsuprine	DL-Propranolol
Caffeine	Ketamine	D-Propoxyphene
Cannabidiol	Ketoprofen	D-Pseudoephedrine
Cannabinol	Labetalol	Quinidine
Chloralhydrate	Levorphanol	Quinine
Chloramphenicol	Loperamide	Ranitidine
Chlordiazepoxide	Maprotiline	Salicylic acid
Chlorothiazide	Meperidine	Secobarbital
( $\pm$ ) -Chlorpheniramine	Meprobamate	Serotonin
Chlorpromazine	Methadone	Sulfamethazine
Chlorquine	Methoxyphenamine	Sulindac
Cholesterol	( $\pm$ ) -3,4-Methylene dioxymphetamine	Temazepam

Clomipramine	hydrochloride(±)-3,4-Methylenedioxymethamphetamine hydrochloride	Tetracycline
Clonidine	Morphine-3-β-D glucuronide	Tetrahydrocortisone 3-(β-D glucuronide)
Codeine	Morphine Sulfate	Tetrahydrozoline
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	DL-Tyrosine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diffunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	DL-Octopamine	DL-Tryptophan
Ecgonine methylester	Oxalic acid	Tyramine
(-) - Ψ-Ephedrine	Oxazepam	Uric acid
Erythromycin	Oxolinic acid	Verapamil
β-Estradiol	Oxycodone	Zomepirac

### THC

4-Acetamidophenol	β-Estradiol	Papaverine
Acetophenetidin	Estrone-3-sulfate	Penicillin-G
N-Acetylprocainamide	Ethyl-p-aminobenzoate	Pentazocine
Acetylsalicylic acid	Fenoprofen	Pentobarbital
Aminopyrine	Furosemide	Perphenazine
Amitriptyline	Gentisic acid	Phencyclidine
Amobarbital	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Phenobarbital
Ampicillin	Hydrochlorothiazide	Phentermine
Ascorbic acid	Hydrocodone	L-Phenylephrine
D,L-Amphetamine	Hydrocortisone	β-Phenylethylamine
L-Amphetamine	O-Hydroxyhippuric acid	β-Phenyllethylamine
Apomorphine	3-Hydroxytyramine	Phenylpropanolamine
Aspartame	Ibuprofen	Prednisolone
Atropine	Imipramine	Prednisone
Benzilic acid	Iproniazid	Procaine

Benzoic acid	(-) Isoproterenol	Promazine
Benzoyllecgonine	Isoxsuprine	Promethazine
Benzphetamine	Ketamine	D,L-Propranolol
Bilirubin	Labetalol	D-Propoxyphene
Brompheniramine	Levorphanol	D-Pseudoephedrine
Caffeine	Loperamide	Quinidine
Chloralhydrate	Maprotiline	Quinine
Chloramphenicol	Meprobamate	Ranitidine
Chlordiazepoxide	Methadone	Salicylic acid
Chlorothiazide	Methoxyphenamine	Secobarbital
(±) Chlorpheniramine	(+) 3,4-Methylenedioxyampheta mine	Serotonin (5-Hydroxytyramine)
Chlorpromazine	(+)3,4-Methylenedioxy metha mphetamine	Sulfamethazine
Chlorquine	Methylphenidate	Sulindac
Cholesterol	Methyprylon	Temazepam
Clomipramine	Morphine-3-β-Dglucuronide	Tetracycline
Clonidine	Nalorphine	Tetrahydrocortisone3 (5-Dglucuronide)
Cocaine hydrochloride	Naloxone	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naltrexone	Thiamine
(-) Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamine
Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diffunisal	Noscapine	Trimipramine
Digoxin	D,L-Octopamine	Tryptamine
Diphenhydramine	Oxalic acid	D, L-Tryptophan
Doxylamine	Oxazepam	Tyramine
Ecgonine hydrochloride	Oxolinic acid	D, L-Tyrosine
Ecgonine methylester	Oxycodone	Uric acid
(-) Y Ephedrine	Oxymetazoline	Verapamil
Erythromycin	p-Hydroxymethamphetamine	Zomepirac

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.

<b>AMP</b> <b>(d-Amphetamine, Cut-off=1000</b> <b>ng/mL)</b>	<b>Result</b>	<b>%</b> <b>Cross-Reactivity</b>
	Positive at 1000 ng/mL	100%
d1-Amphetamine	Positive at 3000 ng/mL	33%
l-Amphetamine	Positive at 20000 ng/mL	5%
(+/-) 3,4-methylene- dioxymphetamine (MDA)	Positive at 20000 ng/mL	5%
Phentermine	Positive at 30000 ng/mL	3%
Hydroxymphetamine	Positive at 8000 ng/mL	12.5%
d-Methamphetamine	>100000	<1%
l-Methamphetamine	>100000	<1%
ephedrine	>100000	<1%
3,4-Methylenedioxyethylamphetamine (MDE)	>100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	>100000	<1%

<b>COC</b> <b>(Benzoylcegonine, Cut-off=300</b> <b>ng/mL)</b>	<b>Result</b>	<b>%</b> <b>Cross-Reactivity</b>
	Positive at 300 ng/mL	100%
Cocaine HCl	Positive at 750 ng/mL	40%
Cocaethylene	Positive at 12500 ng/mL	2.4%
Ecgonine	Positive at 32000 ng/mL	0.9%

<b>THC</b> <b>(11-Nor-<math>\Delta^9</math>-Tetrahydrocannabinol-9-COOH,</b> <b>Cut-off=50 ng/mL)</b>	<b>Result</b>	<b>%</b> <b>Cross-Reactivity</b>
	Positive at 50 ng/mL	100%
11-Hydroxy- $\Delta^9$ -Tetrahydrocannabinol	Positive at 5000 ng/mL	1%
11-Nor- $\Delta^8$ -Tetrahydrocannabinol-9-COOH	Positive at 50	100%

	ng/mL	
Cannabinol	Positive at 20000 ng/mL	0.3%
$\Delta^8$ -Tetrahydrocannabinol	Positive at 10000 ng/mL	0.5%
$\Delta^9$ -Tetrahydrocannabinol	Positive at 10000 ng/mL	0.5%
Cannabidiol	Positive at 20000 ng/mL	0.3%
11-Nor- $\Delta^9$ -THC-carboxy glucuronide	Positive at 2500 ng/mL	2%
(-)-11-nor-9-carboxy- $\Delta^9$ -THC	Positive at 2500 ng/mL	2%

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 SAFECARE Urine Test (Amphetamine, Cocaine and Marijuana) 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 for each drug. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

**AMP**

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

Viewer C	Positive	0	0	2	18	20
	Negative	10	10	18	2	0

**Discordant Results of AMP Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	114130	920	Positive
Viewer B	112663	903	Positive
Viewer B	116513	872	Positive
Viewer C	114130	920	Positive
Viewer C	112663	903	Positive
Viewer A	116032	1086	Negative
Viewer B	113001	1025	Negative
Viewer C	113001	1025	Negative
Viewer C	116032	1086	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	1	19	20
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	2	18	20
	Negative	10	10	18	2	0
Viewer C	Positive	0	0	1	18	20
	Negative	10	10	19	2	0

**Discordant Results of AMP Dip Card**

Viewer	Sample Number	GC/MS Result	Dipcard Format Viewer Results
Viewer A	114130	920	Positive
Viewer B	114130	920	Positive
Viewer B	112663	903	Positive
Viewer C	112663	903	Positive
Viewer A	113001	1025	Negative
Viewer B	113001	1025	Negative
Viewer B	116032	1086	Negative
Viewer C	116032	1086	Negative

<b>Viewer</b>	<b>Sample Number</b>	<b>GC/MS Result</b>	<b>Dipcard Format Viewer Results</b>
<b>Viewer C</b>	111305	1129	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	2	18	20
	Negative	10	10	18	2	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 of AMP Cup**

<b>Viewer</b>	<b>Sample Number</b>	<b>GC/MS Result</b>	<b>Cup Format Viewer Results</b>
<b>Viewer A</b>	112663	903	Positive
<b>Viewer A</b>	116513	872	Positive
<b>Viewer B</b>	114130	920	Positive
<b>Viewer B</b>	112663	903	Positive
<b>Viewer C</b>	114130	920	Positive
<b>Viewer A</b>	116032	1086	Negative
<b>Viewer A</b>	111305	1129	Negative
<b>Viewer B</b>	116032	1086	Negative
<b>Viewer C</b>	113001	1025	Negative

**COC**

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	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	18	20
	Negative	10	10	19	2	0

**Discordant Results of COC Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	126369	294	Positive
Viewer A	125081	293	Positive
Viewer B	126369	294	Positive
Viewer B	125081	293	Positive
Viewer C	126369	294	Positive
Viewer A	123901	325	Negative
Viewer B	124383	319	Negative
Viewer C	123901	325	Negative
Viewer C	124383	319	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	2	18	20
	Negative	10	10	18	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	2	19	20
	Negative	10	10	18	1	0

**Discordant Results of COC DipCard**

Viewer	Sample Number	GC/MS Result	DipCard Format Viewer Results
Viewer A	125081	293	Positive
Viewer A	126518	288	Positive
Viewer B	126369	294	Positive
Viewer C	126369	294	Positive
Viewer C	125081	293	Positive

Viewer	Sample Number	GC/MS Result	DipCard Format Viewer Results
Viewer A	123901	325	Negative
Viewer A	124383	319	Negative
Viewer B	123901	325	Negative
Viewer B	121307	330	Negative
Viewer C	121307	330	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	1	18	20
	Negative	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	2	19	20
	Negative	10	10	18	1	0

#### Discordant Results of COC Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	126369	294	Positive
Viewer B	125081	293	Positive
Viewer C	126369	294	Positive
Viewer C	125081	293	Positive
Viewer A	124383	319	Negative
Viewer A	121307	330	Negative
Viewer B	123901	325	Negative
Viewer B	121307	330	Negative
Viewer C	123901	325	Negative

THC

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	2	18	20
	Negative	10	10	18	2	0
Viewer B	Positive	0	0	2	18	20
	Negative	10	10	18	2	0
Viewer C	Positive	0	0	2	17	20
	Negative	10	10	18	3	0

**Discordant Results of THC Cassette**

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
<b>Viewer A</b>	103932	46	Positive
<b>Viewer A</b>	106313	47	Positive
<b>Viewer B</b>	103587	48	Positive
<b>Viewer B</b>	106313	47	Positive
<b>Viewer C</b>	103587	48	Positive
<b>Viewer C</b>	103932	46	Positive
<b>Viewer A</b>	103201	52	Negative
<b>Viewer A</b>	102396	54	Negative
<b>Viewer B</b>	103201	52	Negative
<b>Viewer B</b>	104659	54	Negative
<b>Viewer C</b>	103201	52	Negative
<b>Viewer C</b>	104659	54	Negative
<b>Viewer C</b>	102396	54	Negative

DipCard 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	2	19	20
	Negative	10	10	18	1	0
Viewer B	Positive	0	0	2	18	20

	Negative	10	10	18	2	0
Viewer C	Positive	0	0	2	18	20
	Negative	10	10	18	2	0

**Discordant Results of THC DipCard**

Viewer	Sample Number	GC/MS Result	DipCard Format Viewer Results
Viewer A	103587	48	Positive
Viewer A	103932	46	Positive
Viewer B	103587	48	Positive
Viewer B	104139	45	Positive
Viewer C	103932	46	Positive
Viewer C	106313	47	Positive
Viewer A	104659	54	Negative
Viewer B	103201	52	Negative
Viewer B	104659	54	Negative
Viewer C	103201	52	Negative
Viewer C	102396	54	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	3	17	20
	Negative	10	10	17	3	0
Viewer B	Positive	0	0	2	18	20
	Negative	10	10	18	2	0
Viewer C	Positive	0	0	2	18	20
	Negative	10	10	18	2	0

**Discordant Results of THC Cup**

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	103587	48	Positive
Viewer A	103932	46	Positive
Viewer A	106313	47	Positive
Viewer B	103587	48	Positive
Viewer B	103932	46	Positive



Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer C	103587	48	Positive
Viewer C	103401	44	Positive
Viewer A	103201	52	Negative
Viewer A	102368	58	Negative
Viewer A	104659	54	Negative
Viewer B	103201	52	Negative
Viewer B	102396	54	Negative
Viewer C	103201	52	Negative
Viewer C	104659	54	Negative

#### Lay-user study

A lay user study was performed at three intended user sites with 420 lay persons testing the amphetamine devices, 420 lay persons testing the cocaine devices and 420 lay persons testing the marijuana devices. A total of 208 females and 212 males tested the amphetamine samples, 205 females and 215 males tested cocaine samples, and 212 females and 208 males tested the marijuana 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 AMP Cup

% of Cutoff	Number of samples	d-Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	250	0	20	100
<b>-50% Cutoff</b>	20	500	0	20	100
<b>-25% Cutoff</b>	20	750	2	18	90
<b>+25% Cutoff</b>	20	1250	17	3	85
<b>+50% Cutoff</b>	20	1500	20	0	100
<b>+75% Cutoff</b>	20	1750	20	0	100

#### Comparison between GC/MS and Lay Person Results AMP Dip Card

% of Cutoff	Number	d-Amphetamine	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 (%)
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	250	0	20	100
<b>-50% Cutoff</b>	20	500	0	20	100
<b>-25% Cutoff</b>	20	750	3	17	85
<b>+25% Cutoff</b>	20	1250	18	2	90
<b>+50% Cutoff</b>	20	1500	20	0	100
<b>+75% Cutoff</b>	20	1750	20	0	100

**Comparison between GC/MS and Lay Person Results AMP Cassette**

% of Cutoff	Number of samples	d-Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	250	0	20	100
<b>-50% Cutoff</b>	20	500	0	20	100
<b>-25% Cutoff</b>	20	750	2	18	90
<b>+25% Cutoff</b>	20	1250	18	2	90
<b>+50% Cutoff</b>	20	1500	20	0	100
<b>+75% Cutoff</b>	20	1750	20	0	100

**Comparison between GC/MS and Lay Person Results COC Cup**

% of Cutoff	Number of samples	Benzoylcegonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	75	0	20	100
<b>-50% Cutoff</b>	20	150	0	20	100
<b>-25% Cutoff</b>	20	225	2	18	90
<b>+25% Cutoff</b>	20	375	18	2	90
<b>+50% Cutoff</b>	20	450	20	0	100
<b>+75% Cutoff</b>	20	525	20	0	100

**Comparison between GC/MS and Lay Person Results COC Dip Card**

% of Cutoff	Number of samples	Benzoylecgonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	75	0	20	100
<b>-50% Cutoff</b>	20	150	0	20	100
<b>-25% Cutoff</b>	20	225	2	18	90
<b>+25% Cutoff</b>	20	375	17	3	85
<b>+50% Cutoff</b>	20	450	20	0	100
<b>+75% Cutoff</b>	20	525	20	0	100

**Comparison between GC/MS and Lay Person Results COC Cassette**

% of Cutoff	Number of samples	Benzoylecgonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	75	0	20	100
<b>-50% Cutoff</b>	20	150	0	20	100
<b>-25% Cutoff</b>	20	225	3	17	85
<b>+25% Cutoff</b>	20	375	17	3	85
<b>+50% Cutoff</b>	20	450	20	0	100
<b>+75% Cutoff</b>	20	525	20	0	100

**Comparison between GC/MS and Lay Person Results THC Cup**

% of Cutoff	Number of samples	11-nor-D9-THC-9-COOH Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	12.5	0	20	100
<b>-50% Cutoff</b>	20	25	0	20	100
<b>-25% Cutoff</b>	20	37.5	2	18	90
<b>+25% Cutoff</b>	20	62.5	18	2	90
<b>+50% Cutoff</b>	20	75	20	0	100
<b>+75% Cutoff</b>	20	87.5	20	0	100

**Comparison between GC/MS and Lay Person Results THC Dip Card**

% of Cutoff	Number of samples	11-nor-D9-THC-9-COOH Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	12.5	0	20	100
<b>-50% Cutoff</b>	20	25	0	20	100
<b>-25% Cutoff</b>	20	37.5	3	17	85
<b>+25% Cutoff</b>	20	62.5	18	2	90
<b>+50% Cutoff</b>	20	75	20	0	100
<b>+75% Cutoff</b>	20	87.5	20	0	100

**Comparison between GC/MS and Lay Person Results THC Cassette**

% of Cutoff	Number of samples	11-nor-D9-THC-9-COOH Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100% Cutoff</b>	20	0	0	20	100
<b>-75% Cutoff</b>	20	12.5	0	20	100
<b>-50% Cutoff</b>	20	25	0	20	100
<b>-25% Cutoff</b>	20	37.5	3	17	85
<b>+25% Cutoff</b>	20	62.5	17	3	85
<b>+50% Cutoff</b>	20	75	20	0	100
<b>+75% Cutoff</b>	20	87.5	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 SAFECARE Urine Test devices are substantially equivalent to the predicate.