May 27, 2020

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

Re: k201120
Trade/Device Name: SAFECARE® Multi-Drug Urine Test Dip Card
SAFECARE® Multi-Drug Urine Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: NFT, NFW, NFY, NGG, NGI, NFV, NGL, PTH, NGM, PTG, QAW, QBF
Dated: April 23, 2020
Received: April 27, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
k201120

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, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) 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 |
| Marijuana | 50 ng/mL |
| Methamphetamine | 1000 ng/mL |
| Morphine | 2000 ng/mL |
| Oxycodone | 100 ng/mL |
| Secobarbital | 300 ng/mL |
| Buprenorphine | 10 ng/mL |
| Methylenedioxy-methamphetamine | 500 ng/mL |
| Phencyclidine | 25 ng/mL |
| Methadone | 300 ng/mL |
| Nortriptyline | 1000 ng/mL |
| d-Propoxyphene | 300 ng/mL |
| 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine | 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 Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone 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, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) 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 |
| Marijuana | 50 ng/mL |
| Methamphetamine | 1000 ng/mL |
| Morphine | 2000 ng/mL |
| Oxycodone | 100 ng/mL |
| Secobarbital | 300 ng/mL |
| Buprenorphine | 10 ng/mL |
| Methylenedioxy-methamphetamine | 500 ng/mL |
| Phencyclidine | 25 ng/mL |
| Methadone | 300 ng/mL |
| Nortriptyline | 1000 ng/mL |
| d-Propoxyphene | 300 ng/mL |
| 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine | 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 Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone 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

510(k) Number: k201120

1. Date: May 27, 2020

2. Submitter: Safecare Biotech (Hangzhou) Co. Ltd.
18 Haishu Road, Yuhang District
Hangzhou, China

3. Contact person: Joe Shia
LSI International Inc.
504E Diamond Ave., Suite I
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com

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 and Cocaine Metabolites Test System | Toxicology (91) |
| NGG Methamphetamine | II | 21 CFR § 862.3610, Methamphetamine Test System | Toxicology (91) |
| NGI Morphine | II | 21 CFR § 862.3640, Morphine Test System | Toxicology (91) |
| NFV Oxazepam | II | 21 CFR § 862.3170, Benzodiazepine Test System | Toxicology (91) |
| NGL Oxycodone | II | 21 CFR § 862.3650, Opiate Test System | Toxicology (91) |
| PTH Secobarbital | II | 21 CFR § 862.3150, Barbiturate Test System | Toxicology (91) |
| NGL Buprenorphine | II | 21 CFR § 862.3650, Opiate Test System | Toxicology (91) |
| NGG Methylenedioxy-methamphetamine | II | 21 CFR § 862.3610, Methamphetamine Test System | Toxicology (91) |
| NGM Phencyclidine | unclassified | Enzyme Immunoassay Phencyclidine | Toxicology (91) |
| PTG Methadone | II | 21 CFR § 862.3620, Methadone Test System | Toxicology (91) |
| QAW Nortriptyline | II | 21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test System | Toxicology (91) |
| QBF Propoxyphene | II | 21 CFR, 862.3700 Propoxyphene Test System | Toxicology (91) |

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| PTG<br>2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine | II | 21 CFR § 862.3620, Methadone Test System | Toxicology (91) |

5. Predicate Device

   The SAFECARE® Multi-Drug Urine Test Dip Card and SAFECARE® Multi-Drug Urine Test Cup (K182654)

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, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) 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 |
| Marijuana | 50 ng/mL |
| Methamphetamine | 1000 ng/mL |
| Morphine | 2000 ng/mL |
| Oxycodone | 100 ng/mL |
| Secobarbital | 300 ng/mL |
| Buprenorphine | 10 ng/mL |
| Methylenedioxy-methamphetamine | 500 ng/mL |
| Phencyclidine | 25 ng/mL |
| Methadone | 300 ng/mL |
| Nortriptyline | 1000 ng/mL |
| d-Propoxyphene | 300 ng/mL |
| 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine | 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 Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone 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, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline d-

Propoxyphene and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) 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 |
| Marijuana | 50 ng/mL |
| Methamphetamine | 1000 ng/mL |
| Morphine | 2000 ng/mL |
| Oxycodone | 100 ng/mL |
| Secobarbital | 300 ng/mL |
| Buprenorphine | 10 ng/mL |
| Methylenedioxy-methamphetamine | 500 ng/mL |
| Phencyclidine | 25 ng/mL |
| Methadone | 300 ng/mL |
| Nortriptyline | 1000 ng/mL |
| d-Propoxyphene | 300 ng/mL |
| 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine | 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 Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene and Oxycodone 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, Cannabinoids, Methamphetamine, Morphine, Secobarbital, Methadone, Methylenedioxymethamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline, Propoxyphen and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (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 Device**

| Item | Device | Predicate - K182654 |
|---|---|---|
| **Indication(s) for Use** | For the qualitative determination of drugs of abuse in human urine. | Same (but the number of drugs detected is different) |
| **Similarities** | | |
| **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 | Same |
| **Differences** | | |
| **Calibrator and Cut-Off Values** | Amphetamine (AMP): 1,000 ng/ml<br>Oxazepam (BZO):300 ng/ml<br>Cocaine (COC): 300 ng/ml<br>11-Nor-$\Delta^9$-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml<br>Methamphetamine (MET): 1,000 ng/ml<br>Morphine (OPI): 2000ng/ml<br>Secobarbital (BAR): 300 ng/ml<br>Methadone (MTD): 300 ng/ml<br>Methylenedioxymethamphetamine (MDMA): 500 ng/ml<br>Oxycodone (OXY): 100 ng/ml<br>Buprenorphine (BUP): 10 ng/ml<br>Phencyclidine (PCP): 25 ng/ml<br>Nortriptyline (TCA): 1000 ng/ml<br>Propoxyphene (PPX): 300 ng/ml<br>2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/mL | Same as candidate device with exclusion of 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/mL |

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

| Item | Device | Predicate - K182654 |
|---|---|---|
| **Indication(s) for Use** | For the qualitative determination of drugs of abuse in human urine. | Same (but the number of drugs detected is different) |
| **Similarities** | | |

| | | |
|---|---|---|
| **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 | Cup |
| **Differences** | | |
| **Calibrator and Cut-Off Values** | Amphetamine (AMP): 1,000 ng/ml<br>Oxazepam (BZO):300 ng/ml<br>Cocaine (COC): 300 ng/ml<br>11-Nor-$\triangle^9$-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml<br>Methamphetamine (MET): 1,000 ng/ml<br>Morphine (OPI): 2000ng/mL<br>Secobarbital (BAR): 300 ng/ml<br>Methadone (MTD): 300 ng/ml<br>Methylenedioxymethamphetamine (MDMA): 500 ng/ml<br>Oxycodone (OXY): 100 ng/ml<br>Buprenorphine (BUP): 10 ng/ml<br>Phencyclidine (PCP): 25 ng/ml<br>Nortriptyline (TCA): 1000 ng/ml<br>Propoxyphene (PPX): 300 ng/ml<br>2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/mL | Same as candidate device with exclusion of 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP): 300 ng/mL |

9. Test Principle

The SAFECARE® Dip Card Tests, and SAFECARE® Cup Tests are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital, Methadone, Methylenedioxymethamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline, Propoxyphen and 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine 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 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine. Please refer to k182654 for precision data for Methylenedioxy-Methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene, and to k181968 for precision data for Oxazepam, Methamphetamine, Morphine, Secobarbital and Methadone, and to k153646 for precision data for Amphetamine, Cocaine, and Cannabinoids.

**2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine**

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+ | 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- |

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+ | 27-/23+ | 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+ | 26-/24+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

The cut-off value of 300 ng/mL for 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine is verified.

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, with the exception of albumin with no interference at a concentration of 100mg/dL and ethanol at 1% volume, are summarized in the following tables. There were no differences observed between the SAFECARE® Cup and Dip Card formats.

| | | |
|---|---|---|
| Acetominophen (4-Acetamidophenol) | Ecgonine methyl ester | D,L-Octopamine |
| Acetophenetidin | Erythromycin | Oxalic acid |
| N-Acetylprocainamide | β-Estradiol | Oxolinic acid |
| Acetylsalicylic acid | Ethanol (1% vol) | Oxymetazoline |
| Albumin (100mg/dL) | 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 | Meperidine | Thiamine |
| Cortisone | Meprobamate | Thioridazine |
| (-) Cotinine | Methoxyphenamine | Triamterene |
| Creatinine | Nalidixic acid | DL-Tyrosine |
| Deoxycorticosterone | Naloxone | Trifluoperazine |
| Dextromethorphan | Naltrexone | Trimethoprim |
| Diclofenac | Naproxen | D L-Tryptophan |
| Diflunisal | Niacinamide | Tyramine |
| Digoxin | Nifedipine | Uric acid |
| Diphenhydramine | Norethindrone | Verapamil |
| Disopyramide | Noscapine | Zomepirac |

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 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine. The rest of the data were reported in k182654 for Methylenedioxy-Methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene, and k181968 for Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital and Methadone. There were no differences observed between the SAFECARE® Cup and Dip Card formats.

| **Compounds** | **Result Positive at(ng/ml)** | **% Cross-Reactivity** |
|---|---|---|
| Methadone | 300000 | 0.1% |

| | | |
|---|---|---|
| EMDP | 300000 | 0.1% |
| Doxylamine | >100,000 | <0.3% |
| Disopyramide | >100,000 | <0.3% |
| LAAM (Levo-alpha-acetylmethadol) HCl | >100,000 | <0.3% |
| Alpha Methadol | >100,000 | <0.3% |

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 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP). The rest data were reported in k182654 for Methylenedioxy-Methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene, and in k181968 for Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Secobarbital and Methadone.

**EDDP**

| 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 | 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 A** | CM2632 | 291 | Positive |
| **Viewer B** | CM9474 | 309 | 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 | 20 | 20 |
| | Negative | 10 | 10 | 19 | 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 | Cup Viewer Results |
|---|---|---|---|
| **Viewer A** | CM1684 | 285 | Positive |
| **Viewer B** | CM2850 | 372 | Negative |

Lay-user study:

A lay user study was performed at three intended user sites with 310 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. Typical results are shown below.

**AMP:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 253 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 496 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 753 | 2 | 18 | 90 |
| **+25% Cutoff** | 20 | 1249 | 17 | 3 | 85 |
| **+50% Cutoff** | 40 | 1498 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 1758 | 20 | 0 | 100 |

**COC:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 76 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 147 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 226 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 372 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 449 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 524 | 20 | 0 | 100 |

**THC:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 12 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 24 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 36 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 63 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 75 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 88 | 20 | 0 | 100 |

**BAR:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 76 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 147 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 225 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 374 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 449 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 524 | 20 | 0 | 100 |

**BZO:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 76 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 147 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 227 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 374 | 19 | 1 | 95 |
| **+50% Cutoff** | 40 | 450 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 526 | 20 | 0 | 100 |

**MET:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 248 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 497 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 749 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 1251 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 1499 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 1754 | 20 | 0 | 100 |

**MTD:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 76 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 147 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 223 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 374 | 17 | 3 | 85 |
| **+50% Cutoff** | 40 | 450 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 526 | 20 | 0 | 100 |

**OPI:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 501 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 999 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 1501 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 2499 | 19 | 1 | 95 |
| **+50% Cutoff** | 40 | 2999 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 3501 | 20 | 0 | 100 |

**MDMA:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 126 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 248 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 375 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 624 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 748 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 877 | 20 | 0 | 100 |

**OXY:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 25 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 48 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 74 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 126 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 150 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 176 | 20 | 0 | 100 |

**BUP:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 3 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 5 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 8 | 2 | 18 | 90 |
| **+25% Cutoff** | 20 | 13 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 15 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 18 | 20 | 0 | 100 |

**PCP:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 6 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 12 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 19 | 2 | 18 | 90 |
| **+25% Cutoff** | 20 | 32 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 37 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 43 | 20 | 0 | 100 |

**TCA:**

| % of Cutoff | Number of samples | Drug Concentration by LC/MS(ng/mL) | Lay person Results | | The percentage of correct results (%) |
|---|---|---|---|---|---|
| | | | No. of Positive | No. of Negative | |
| **-100% Cutoff** | 20 | 0 | 0 | 20 | 100 |
| **-75% Cutoff** | 20 | 250 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 497 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 750 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 1249 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 1500 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 1749 | 20 | 0 | 100 |

**PPX:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 76 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 148 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 223 | 3 | 17 | 85 |
| **+25% Cutoff** | 20 | 374 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 448 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 525 | 20 | 0 | 100 |

**EDDP:**

| % of Cutoff | Number of samples | Drug Concentration by LC/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 | 76 | 0 | 20 | 100 |
| **-50% Cutoff** | 170 | 152 | 0 | 170 | 100 |
| **-25% Cutoff** | 20 | 226 | 1 | 19 | 95 |
| **+25% Cutoff** | 20 | 375 | 18 | 2 | 90 |
| **+50% Cutoff** | 40 | 452 | 40 | 0 | 100 |
| **+75% Cutoff** | 20 | 526 | 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.