Guangzhou Decheng Biotechnology Co., Ltd.
Mango Huang
Regulatory Affairs Manager
Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road
Science City, Huangpu District
Guangzhou, 510663
China

Re: K240698
Trade/Device Name: Dochek® Multi-Drug Urine Test Dipcard Rx; Dochek® Multi-Drug Urine Test Dipcard
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, NFT, DKZ, PTH, DIS, NGL, NFV, JXM, NFY, DIO, PTG, DJR, NGG, DJC, NGM, LCM, QBF, JXN, QAW, LFG, NFW, LDJ
Dated: March 14, 2024
Received: March 14, 2024

Dear Mango Huang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph A. Kotarek -S
Digitally signed by Joseph A. Kotarek -S
Date: 2024.05.09 14:56:49 -04'00'

Joseph Kotarek
Branch Chief

Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K240698

Device Name
Dochek® Multi-Drug Urine Test Dipcard Rx

Indications for Use *(Describe)*
Dochek® Multi-Drug Urine Test Dipcard Rx is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations:

| Drug (Identifier) | Cut-off level |
|---|---|
| Amphetamine (AMP) | 1000 or 500 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 300 or 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Methamphetamine (MET) | 1000 or 500 ng/mL |
| Morphine (MOP/OPI) | 300 or 2000 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Cannabinoids (THC) | 50 ng/mL |
| 6-Monoacetylmorphine (6-MAM) | 10 ng/mL |

Dochek® Multi-Drug Urine Test Dipcard Rx offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device. It is intended for prescription use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
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510(k) Number *(if known)*
K240698

Device Name
Dochek® Multi-Drug Urine Test Dipcard

Indications for Use *(Describe)*
Dochek® Multi-Drug Urine Test Dipcard is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations:

| Drug (Identifier) | Cut-off level |
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| Amphetamine (AMP) | 1000 or 500 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
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| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Methamphetamine (MET) | 1000 or 500 ng/mL |
| Morphine (MOP/OPI) | 300 or 2000 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Cannabinoids (THC) | 50 ng/mL |
| 6-Monoacetylmorphine (6-MAM) | 10 ng/mL |

Dochek® Multi-Drug Urine Test Dipcard offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device. It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

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# 510(k) SUMMARY

**510(k) number: k240698**

**1. Date:** May 9, 2024

**2. Submitter:**
Submitter: Guangzhou Decheng Biotechnology Co., Ltd.
Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China
Contact Person: Mango Huang
Contact Email Address: mango.huang@dochekbio.com
Telephone: +86-020-82557192

**3. Correspondent:**
Correspondent: Guangzhou Decheng Biotechnology Co., Ltd.
Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China
Contact Person: Mango Huang
Contact Email Address: mango.huang@dochekbio.com
Telephone: (888) 695-5248

**4. Device Name:** Dochek® Multi-Drug Urine Test Dipcard Rx
Dochek® Multi-Drug Urine Test Dipcard

**5. Classification:** Class II

| **Product Code**<br>**Target Drug** | **Regulation Section** | **Panel** |
|---|---|---|
| DKZ, NFT<br>Amphetamine (AMP) | 862.3100, Amphetamine Test System | Toxicology |
| DIS, PTH<br>Secobarbital (BAR) | 862.3150, Barbiturate Test System | Toxicology |
| DJG, NGL<br>Buprenorphine (BUP)<br>Morphine (MOP/OPI)<br>Oxycodone (OXY)<br>6-Monoacetylmorphine (6-MAM) | 862.3650, Opiate Test System | Toxicology |
| JXM, NFV<br>Oxazepam (BZO) | 862.3170, Benzodiazepine Test System | Toxicology |
| DIO, NFY<br>Cocaine (COC) | 862.3250, Cocaine and cocaine metabolite test system | Toxicology |
| DJR, PTG<br>2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)<br>Methadone (MTD) | 862.3620, Methadone Test System | Toxicology |

| | | |
|---|---|---|
| DJC, NGG<br>Methylenedioxymethamphetamine (MDMA)<br>Methamphetamine (MET) | 862.3610,<br>Methamphetamine Test System | Toxicology |
| LCM, NGM<br>Phencyclidine (PCP) | Unclassified | Toxicology |
| JXN, QBF<br>Propoxyphene (PPX) | 862.3700 Propoxyphene test system. | Toxicology |
| LFG, QAW<br>Nortriptyline (TCA) | 862.3910 Tricyclic antidepressant drugs test system | Toxicology |
| LDJ, NFW<br>Cannabinoids (THC) | 862.3870, Cannabinoids Test System | Toxicology |

## 6. Predicate Devices

| | |
|---|---|
| K232659 | Dochek® Multi-Drug Urine Test Cup Rx<br>Dochek® Multi-Drug Urine Test Cup |

## 7. Intended Use

Dochek® Multi-Drug Urine Test Dipcard Rx is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 1000 or 500 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 300 or 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Methamphetamine (MET) | 1000 or 500 ng/mL |
| Morphine (MOP/OPI) | 300 or 2000 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Cannabinoids (THC) | 50 ng/mL |
| 6-Monoacetylmorphine (6-MAM) | 10 ng/mL |

Dochek® Multi-Drug Urine Test Dipcard Rx offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device.

**It is intended for prescription use. For in vitro diagnostic use only.**

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

Dochek® Multi-Drug Urine Test Dipcard is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the following cutoff concentrations:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 1000 or 500 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 300 or 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Methamphetamine (MET) | 1000 or 500 ng/mL |
| Morphine (MOP/OPI) | 300 or 2000 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Cannabinoids (THC) | 50 ng/mL |
| 6-Monoacetylmorphine (6-MAM) | 10 ng/mL |

Dochek® Multi-Drug Urine Test Dipcard offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device.
**It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.**

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

## 8. Device Description

Dochek® Multi-Drug Urine Test Dipcard Rx and Dochek® Multi-Drug Urine Test Dipcard are immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine at or above the cut-off levels as indicated. The products are single-use in vitro diagnostic devices.
This device is a dipcard format in which the test strips are integrated into the plastic dipcard. After removing the cap of the dipcard, the absorbent end of the test strips is exposed and can be in direct

contact with the urine sample. The device is in a ready-to-use format and no longer requires assembly before use.

## 9. Substantial Equivalence Information

| Similarities | | | |
|---|---|---|---|
| **Item** | **New Device** | | **Predicate Device (K232659)** |
| **Intended use** | Qualitative detection of drugs of abuse in urine.<br>For prescription use or over-the-counter use | | Same |
| **Methodology** | Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction | | Same |
| **Type of Test** | Qualitative | | Same |
| **Specimen Type** | Human urine | | Same |
| **Target Drug and Cutoff Value** | **Target Drug** | **Cutoff (ng/mL)** | Same |
| | Amphetamine (AMP) | 1000 or 500 | |
| | Secobarbital (BAR) | 300 | |
| | Buprenorphine (BUP) | 10 | |
| | Oxazepam (BZO) | 300 | |
| | Cocaine (COC) | 300 or 150 | |
| | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 | |
| | Methylenedioxymethamphetamine (MDMA) | 500 | |
| | Methamphetamine (MET) | 1000 or 500 | |
| | Morphine (MOP300/OPI2000) | 2000 or 300 | |
| | Methadone (MTD) | 300 | |
| | Oxycodone (OXY) | 100 | |
| | Phencyclidine (PCP) | 25 | |
| | Propoxyphene (PPX) | 300 | |
| | Nortriptyline (TCA) | 1000 | |
| | Cannabinoids (THC) | 50 | |
| | 6-Monoacetylmorphine (6-MAM) | 10 | |
| Differences | | | |
| **Configurations** | Test dipcard | | Test cup |

## 10. Standard/Guidance Document Reference (if applicable)

None referenced.

## 11. Test Principle

Dochek® Multi-Drug Urine Test Dipcard Rx or Dochek® Multi-Drug Urine Test Dipcard is a

competitive immunoassay that is used to screen for the presence of various drugs and drug metabolites in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.
When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug in the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.
When drug level is at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

## 12. Performance Characteristics

### A. Analytical Performance

#### a. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Other samples were prepared by spiked target drug in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test dipcard. The results obtained are summarized in the following tables:

| Drug | Lot Number | +100% cutoff | +75% cutoff | +50% cutoff | +25% cutoff | Cutoff | -25% cutoff | -50% cutoff | -75% cutoff | -100% cut-off |
|---|---|---|---|---|---|---|---|---|---|---|
| AMP 1000 | Lot I | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot II | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot III | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BAR 300 | Lot I | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot II | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot III | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BUP 10 | Lot I | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 16-/34+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot II | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot III | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BZO 300 | Lot I | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot II | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot III | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot I | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **COC 300** | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **EDDP 300** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **MDMA 500** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **MET 1000** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **OPI 2000** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **MTD 300** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **OXY 100** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **PCP 25** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 16-/34+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **PPX 300** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **TCA 1000** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **THC 50** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **6-MAM** | **Lot I** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot II** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot III** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **AMP 500** | **Lot IV** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot V** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot VI** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **COC 150** | **Lot IV** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot V** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot VI** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **MET 500** | **Lot IV** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot V** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot VI** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| **MOP 300** | **Lot IV** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot V** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 15-/35+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | **Lot VI** | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 14-/36+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |

**b. Linearity/assay reportable range:**

Not applicable. This device is intended for qualitative use only.

**c. Stability:**

The device can be stable at 2-30℃ for 36 months based on real time stability study.

**d. Detection limit:**

Not applicable.

**e. Analytical specificity/Interference:**

**Cross-Reactivity:**

Analytical specificity for this device was determined through adding the potential interfering substances to drug-free urine samples. The relative cross-reactivity represents the minimum concentration necessary to yield a result similar to the cutoff level of the respective assay. Percent cross-reactivity, provided in the below table, was calculated as the concentration of analyte tested that yielded a positive result, divided by the cutoff concentration, multiplied by 100. If no cross reactivity was observed, the highest concentration tested is shown.

| **Drug/Cutoff** | **Compound** | **Concentration (ng/mL)** | **% Cross-Reactivity** |
|---|---|---|---|
| AMP 1000 | d-Amphetamine | 1,000 | 100% |
| | d/l-Amphetamine | 3,000 | 33.3% |
| | l-Amphetamine | 50,000 | 2% |
| | (+/-) 3,4-methylenedioxyamphetamine (MDA) | 5,000 | 20% |
| | Phentermine | 3,000 | 33.3% |
| | Hydroxyamphetamine | 10,000 | 10% |
| | d-Methamphetamine | 100,000(Negative) | Not detected |
| | l-Methamphetamine | 100,000(Negative) | Not detected |

| | | | |
|---|---|---|---|
| | (+/-)3,4-Methylenedioxyethylamphetamine (MDEA) | 100,000(Negative) | Not detected |
| | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 100,000(Negative) | Not detected |
| | (1R,2S)-(-)-Ephedrine | 100,000(Negative) | Not detected |
| | β-Phenylethylamine | 100,000 | 1% |
| | Tyramine | 100,000 | 1% |
| | p-Hydroxynorephedrine | 100,000 | 1% |
| | Phenylpropanolamine | 100,000(Negative) | Not detected |
| | (±)Phenylpropanolamine | 100,000(Negative) | Not detected |
| | p-Hydroxyamphetamine | 100,000 | 1% |
| | d/l-Norephedrine | 100,000 | 1% |
| | Benzphetamine | 100,000(Negative) | Not detected |
| | l-Epinephrine | 100,000(Negative) | Not detected |
| | d/l-Epinephrine | 100,000(Negative) | Not detected |
| BAR 300 | Secobarbital | 300 | 100% |
| | Amobarbital | 1,000 | 30% |
| | Alphenal | 75 | 400% |
| | Aprobarbital | 250 | 120% |
| | Butabarbital | 100 | 300% |
| | Butalbital | 5,000 | 6% |
| | Butethal | 500 | 60% |
| | Cyclopentobarbital | 500 | 60% |
| | Pentobarbital | 200 | 150% |
| | Phenobarbital | 300 | 100% |
| BUP 10 | Buprenorphine | 10 | 100% |
| | Norbuprenorphine | 50 | 20% |
| | Buprenorphine 3-D-glucuronide | 10 | 100% |
| | Norbuprenorphine 3-D-glucuronide | 10 | 100% |
| | Morphine | 100000 (Negative) | Not Detected |
| | Oxymorphone | 100000 (Negative) | Not Detected |

| | | | |
|---|---|---|---|
| | Hydromorphone | 100000 (Negative) | Not Detected |
| BZO 300 | Oxazepam | 300 | 100% |
| | Alprazolam | 150 | 200% |
| | α-Hydroxyalprazolam | 1,500 | 20% |
| | Bromazepam | 100 | 300% |
| | Chlordiazepoxide | 500 | 60% |
| | Clobazam | 750 | 40% |
| | Clonazepam | 1,500 | 20% |
| | Clorazepate dipotassium | 100 | 300% |
| | Diazepam | 500 | 60% |
| | Estazolam | 500 | 60% |
| | Flunitrazepam | 2,500 | 12% |
| | Midazolam | 2,000 | 15% |
| | Nitrazepam | 2,000 | 15% |
| | Nordiazepam | 500 | 60% |
| | Temazepam | 250 | 120% |
| | Triazolam | 1,000 | 30% |
| | Desalkylflurazepam | 500 | 60% |
| | Lorazepam | 5,000 | 6% |
| | Norchlordiazepoxide | 500 | 60% |
| | Nordazepam | 1,000 | 30% |
| | Delorazepam | 2,000 | 15% |
| | Demoxepam | 5,000 | 6% |
| | Flurazepam | 500 | 60% |
| COC 300 | Benzoylecgonine | 300 | 100% |
| | Cocaine HCl | 750 | 40% |
| | Cocaethylene | 12,500 | 2.4% |
| | Ecgonine | 30,000 | 1% |
| | Ecgonine methyl ester | 100,000(negative) | Not detected |
| | Norcocaine | 100,000(negative) | Not detected |
| EDDP 300 | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 | 100% |
| | Methadone | 100,000(negative) | Not detected |
| | EMDP | 100,000(negative) | Not detected |

| | | | |
|---|---|---|---|
| | Doxylamine | 100,000(negative) | Not detected |
| | Levacetylmethadol (LAAM) | 100,000(negative) | Not detected |
| | Disopyramide | 100,000(negative) | Not detected |
| | Alpha Methadol | 100,000(negative) | Not detected |
| MDMA 500 | (+/-)3,4-Methylenedioxymethamphetamine HCl(MDMA) | 500 | 100% |
| | (+/-)3,4-Methylenedioxyamphetamine HCl (MDA) | 3,000 | 17% |
| | (+/-)3,4-Methylenedioxyethylamphetamine (MDEA) | 300 | 167% |
| | d-Methamphetamine | 100,000(Negative) | Not detected |
| | d-Amphetamine | 100,000(Negative) | Not detected |
| | l-Methamphetamine | 100,000(Negative) | Not detected |
| | l-Amphetamine | 100,000(Negative) | Not detected |
| MET 1000 | d-Methamphetamine | 1,000 | 100% |
| | d-Amphetamine | 50,000 | 2% |
| | Chloroquine | 50,000 | 2% |
| | (1R,2S)-(-)-Ephedrine | 50,000 | 2% |
| | (-)-Methamphetamine | 25,000 | 4% |
| | (+/-)3,4-methylenedioxumethamphetamine (MDMA) | 4,000 | 25% |
| | β-Phenylethylamine | 50,000 | 2% |
| | Trimethobenzamide | 10,000 | 10% |
| | l-Amphetamine | 75,000 | 1.3% |
| | (+/-)3,4-Methylenedioxyethylamphetamine (MDEA) | 30,000 | 3.3% |
| | Mephentermine | 50,000 | 2% |
| | Methoxyphenamine | 50,000 | 2% |
| | Fenfluramine | 75,000 | 1.3% |

| | | | |
|---|---|---|---|
| | Procaine | 100,000(Negative) | Not detected |
| | d/l-Amphetamine | 100,000(Negative) | Not detected |
| | p-Hydroxymethamphetamine | 30,000 | 3.3% |
| | l-Phenylephrine | 100,000(Negative) | Not detected |
| | d/l-Methamphetamine | 1,000 | 100% |
| | (+/-) 3,4-Methylenedioxyamphetamine (MDA) | 100,000(Negative) | Not detected |
| OPI 2000 | Morphine | 2,000 | 100% |
| | Codeine | 2,000 | 100% |
| | Hydrocodone | 12,500 | 16% |
| | Hydromorphone | 5,000 | 40% |
| | 6-Monoacetylmorphine | 1,500 | 133% |
| | Morphine 3-β-D-glucuronide | 2,000 | 100% |
| | Ethylmorphine | 1,500 | 133% |
| | Diacetylmorphine (heroin) | 2,000 | 100% |
| | Levorphanol | 75,000 | 2.7% |
| | Norcodeine | 12,500 | 16% |
| | Oxycodone | 100,000(Negative) | Not detected |
| | Thebaine | 5,000 | 40% |
| | Normorphine | 50,000 | 4% |
| | Oxymorphone | 100,000(Negative) | Not detected |
| | Procaine | 100,000(Negative) | Not detected |
| | Codeine-6-β-D-glucuronide | 3,000 | 67% |
| | d-Norpropoxyphene hydrochloride | 5,000 | 40% |
| MTD 300 | Methadone | 300 | 100% |
| | EDDP | 100,000(Negative) | Not detected |
| | Doxylamine | 50,000 | 0.6% |
| | Levacetylmethadol (LAAM) | 100,000(negative) | Not detected |
| | EMDP | 100,000(negative) | Not detected |
| | Alpha Methadol | 100,000(negative) | Not detected |
| OXY 100 | Oxycodone | 100 | 100% |
| | Hydrocodone | 5,000 | 2% |
| | Hydromorphone | 50,000 | 0.2% |

| | | | |
|---|---|---|---|
| | Oxymorphone | 1,000 | 10% |
| | Codeine | >100,000 | Not detected |
| | Ethylmorphine | >100,000 | Not detected |
| | Dihydrocodeine | 20,000 | 0.5% |
| | Oxymorphone-3β-D- glucuronide | 5,000 | 2% |
| | Morphine | 100,000(negative) | Not detected |
| | 6-Monoacetylmorphine | 100,000(negative) | Not detected |
| | Buprenorphine | 100,000(negative) | Not detected |
| | Thebaine | 100,000(negative) | Not detected |
| PCP 25 | Phencyclidine | 25 | 100% |
| | 4-Hydroxy Phencyclidine | 1,500 | 1.7% |
| PPX 300 | d-Propoxyphene | 300 | 100% |
| | d-Norpropoxyphene | 300 | 100% |
| TCA 1000 | Nortriptyline | 1,000 | 100% |
| | Nordoxepin | 1,000 | 100% |
| | Trimipramine | 3,000 | 33.3% |
| | Promazine | 1,500 | 66.7% |
| | Desipramine | 200 | 500% |
| | Imipramine | 750 | 133% |
| | Clomipramine | 10,000 | 10% |
| | Doxepin | 1,250 | 80% |
| | Maprotiline | 2,000 | 50% |
| | Amitriptyline | 1,500 | 66.7% |
| | Promethazine | 25,000 | 4% |
| | Cyclobenzaprine | 1,000 | 100% |
| | Norclomipramine | 12,500 | 8% |
| THC 50 | 11-nor-Δ9-THC-9-COOH | 50 | 100% |
| | 11-nor-Δ8-THC-9-COOH | 30 | 167% |
| | (±)-11-Hydroxy-Δ9-THC | 2,500 | 2% |
| | Δ8- Tetrahydrocannabinol | 2,000 | 2.5% |
| | Δ9- Tetrahydrocannabinol | 5,000 | 1% |
| | Cannabinol | 10,000 | 0.5% |
| | Cannabidiol(CBD) | 100,000 | 0.05% |
| | (±)-11-nor-9-carboxy-Δ9-THC | 100 | 50% |

| | | | |
|---|---|---|---|
| | 11-nor-Δ9-THC-carboxy glucuronide | 100 | 50% |
| 6-MAM 10 | 6-Monoacetylmorphine | 10 | 100% |
| | Codeine | 100,000(Negative) | Not detected |
| | Ethylmorphine | 100,000(Negative) | Not detected |
| | Hydrocodone | 50,000 | 0.02% |
| | Hydromorphone | 10,000 | 0.1% |
| | Levorphanol | 100,000(Negative) | Not detected |
| | Morphine 3-β-D-glucuronide | 100,000(Negative) | Not detected |
| | Morphine | 100,000 | 0.01% |
| | Norcodeine | 100,000(Negative) | Not detected |
| | Normorphine | 100,000(Negative) | Not detected |
| | Oxycodone | 100,000(Negative) | Not detected |
| | Oxymorphone | 10,000 | 0.1% |
| | Procaine | 50,000 | 0.02% |
| | Thebaine | 10,000 | 0.1% |
| | Diacetylmorphine (heroin) | 25 | 40% |
| | Acetylcodeine | 10,000(Negative) | <0.1% |
| | Buprenorphine | 10,000(Negative) | <0.1% |
| | Dihydrocodeine | 10,000(Negative) | <0.1% |
| | Nalorphine | 5,000 | 0.2% |
| | Dextromethorphan | 100,000(Negative) | Not detected |
| | Imipramine | 100,000(Negative) | Not detected |
| | Levacetylmethadol (LAAM) | 100,000(Negative) | Not detected |
| | Meperidine | 100,000(Negative) | Not detected |
| | Methadone | 100,000(Negative) | Not detected |
| | Mitragynine (kratom) | 20,000(Negative) | <0.05% |
| | Morphine 6-D-glucuronide | 100,000(Negative) | Not detected |
| | Naloxone | 100,000(Negative) | Not detected |
| | Naltrexone | 100,000(Negative) | Not detected |
| | Naproxen | 100,000(Negative) | Not detected |
| | Norbuprenorphine | 10,000(Negative) | <0.1% |
| | Norbuprenorphine glucuronide | 100,000(Negative) | Not detected |
| | Norhydrocodone | 100,000(Negative) | Not detected |

| | | | |
|---|---|---|---|
| | Noroxycodone | 100,000(Negative) | Not detected |
| | Noroxymorphone | 100,000(Negative) | Not detected |
| | Norpropoxyphene | 100,000(Negative) | Not detected |
| | Oxymorphone-3β-D- glucuronide | 100,000(Negative) | Not detected |
| | Tapentadol HCl | 100,000(Negative) | Not detected |
| | Tramadol | 100,000(Negative) | Not detected |
| AMP 500 | d-Amphetamine | 500 | 100% |
| | d/l-Amphetamine | 1,500 | 33.3% |
| | l-Amphetamine | 25,000 | 2% |
| | (+/-) 3,4-methylenedioxyamphetamine (MDA) | 2,500 | 20% |
| | Phentermine | 1,500 | 33.3% |
| | Hydroxyamphetamine | 5,000 | 10% |
| | d-Methamphetamine | 100,000(Negative) | Not detected |
| | l-Methamphetamine | 100,000(Negative) | Not detected |
| | (+/-)3,4-Methylenedioxyethylamphetamine (MDEA) | 100,000(Negative) | Not detected |
| | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 100,000(Negative) | Not detected |
| | (1R,2S)-(-)-Ephedrine | 100,000(Negative) | Not detected |
| | β-Phenylethylamine | 100,000 | 0.5% |
| | Tyramine | 100,000 | 0.5% |
| | p-Hydroxynorephedrine | 100,000 | 0.5% |
| | Phenylpropanolamine | 100,000(Negative) | Not detected |
| | (±)Phenylpropanolamine | 100,000(Negative) | Not detected |
| | p-Hydroxyamphetamine | 100,000 | 0.5% |
| | d/l-Norephedrine | 100,000 | 0.5% |
| | Benzphetamine | 100,000(Negative) | Not detected |
| | l-Epinephrine | 100,000(Negative) | Not detected |
| | d/l-Epinephrine | 100,000(Negative) | Not detected |
| COC 150 | Benzoylecgonine | 150 | 100% |

| | | | |
|---|---|---|---|
| | Cocaine HCl | 500 | 30% |
| | Cocaethylene | 5,000 | 3% |
| | Ecgonine | 15,000 | 1% |
| | Ecgonine methyl ester | 100,000(negative) | Not detected |
| | Norcocaine | 100,000(negative) | Not detected |
| MET 500 | d-Methamphetamine | 500 | 100% |
| | d-Amphetamine | 25,000 | 2% |
| | Chloroquine | 25,000 | 2% |
| | (1R,2S)-(-)-Ephedrine | 25,000 | 2% |
| | (-)-Methamphetamine | 12,500 | 4% |
| | (+/-)3,4-methylenedioxumethamphetamine (MDMA) | 2,000 | 25% |
| | β-Phenylethylamine | 25,000 | 2% |
| | Trimethobenzamide | 5,000 | 10% |
| | l-Amphetamine | 50,000 | 1% |
| | (+/-)3,4-Methylenedioxyethylamphetamine (MDEA) | 15,000 | 3.3% |
| | Mephentermine | 25,000 | 2% |
| | Methoxyphenamine | 25,000 | 2% |
| | Fenfluramine | 37,500 | 1.3% |
| | Procaine | >100,000 | Not detected |
| | d/l-Amphetamine | 75,000 | 0.7% |
| | p-Hydroxymethamphetamine | 15,000 | 3.3% |
| | l-Phenylephrine | >100,000 | Not detected |
| | d/l-Methamphetamine | 500 | 100% |
| | (+/-) 3,4-Methylenedioxyamphetamine (MDA) | 75,000 | 0.7% |
| MOP 300 | Morphine | 300 | 100% |
| | Codeine | 300 | 100% |
| | Hydrocodone | 5,000 | 6% |
| | Hydromorphone | 1,000 | 30% |

| | | | |
|---|---|---|---|
| | 6-Monoacetylmorphine | 150 | 200% |
| | Morphine 3-β-D-glucuronide | 1,000 | 30% |
| | Ethylmorphine | 100 | 300% |
| | Diacetylmorphine (heroin) | 300 | 100% |
| | Levorphanol | 10,000 | 3% |
| | Norcodeine | 5,000 | 6% |
| | Oxycodone | 75,000 | 0.4% |
| | Thebaine | 3,000 | 10% |
| | Normorphine | 3,000 | 10% |
| | Oxymorphone | 25,000 | 1.2% |
| | Procaine | 100,000(Negative) | Not detected |
| | Codeine-6-β-D-glucuronide | 500 | 60% |
| | d-Norpropoxyphene hydrochloride | 300 | 100% |

**Interfering Substances:**

To evaluate potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 25% below and 25% above each corresponding cutoff. Compounds that show no interference at a concentration of 100μg/mL are summarized in the following table.

| | | |
|---|---|---|
| 3-Hydroxytyramine | Diflunisal | Oxalic Acid |
| Acetaminophen | Digoxin | Oxolinic Acid |
| Acetylsalicylic Acid | Diphenhydramine | Oxymetazoline |
| Acyclovir | Dopamine HCl | Paliperidone |
| Albumin (100 mg/dL) | D-Pseudoephedrine | Papaverine |
| Albuterol sulfate (Proair HFA) | Duloxetine | Penicillin-G |
| Aminophylline | Erythromycin | PenicillinV Potassium |
| Aminopyrine | Esomeprazole Magnesium | Phenacetin (Acetophenetidin) |
| Amoxicillin | Ethanol (1%) | Phenelzine |
| Ampicillin | Fenoprofen | Prednisone |
| Apomorphine | Fluoxetine Hydrochloride | Pregablin |
| Aripiprazole | Furosemide | Quinine |
| Aspartame | Gabapentin | Ranitidine |
| Atomoxetine | Gentisic Acid | Rifampicin |
| Atorvastatin Calcium | Glucose | Risperidone |

| | | |
|---|---|---|
| Atropine | Hemoglobin | Salicylic Acid |
| Azithromycin | Hydralazine | Serotonin |
| Benzilic acid | Hydrochlorothiazide | Sertraline Hydrochloride |
| Benzocaine | Hydrocortisone | Sildenafil Citrate |
| Benzoic acid | Ibuprofen | Simvastatin |
| Bilirubin | Isoxsuprine | Sulfamethazine |
| Bupropion | Ketamine | Sulindac |
| Captopril | Ketoprofen | Tetrahydrozoline |
| Carbamazepine | Labetalol | Theophylline |
| Cefradine | Levofloxacin Hydrochloride | Thiamine |
| Cephalexin | Levonorgestrel | Thioridazine |
| Chloral Hydrate | Levothyroxine Sodium | Tramadol Hydrochloride |
| Chloramphenicol | Lidocaine Hydrochloride | Trazodone Hydrochloride |
| Chlorothiazide | Lisinopril | Triamterene |
| chlorpheniramine | Loperamide | Trifluoperazine |
| Cholesterol | Loratadine | Trimethoprim |
| Ciprofloxacin Hydrochloride | Magnesium | Uric Acid |
| Citalopram | Meperidine | Venlafaxine HCl |
| Clarithromycin | Meprobamate | Verapamil |
| Clonidine | Metoprolol Tartrate | Vitamin B2 |
| Clozapine | Mifepristone | Vitamin C (Ascorbic acid) |
| Conjugated Estrogens | N-Acetylprocainamide | Zomepirac |
| Cortisone | Nalidixic Acid | β-Estradiol |
| Cotinine | Naproxen | Chlorpromazine |
| Creatinine | Niacinamide | Perphenazine |
| D,L- Isoproterenol | Nicotine | Tetrahydrocortisone 3-(β-D-glucuronide) |
| D,L-Octopamine | Nifedipine | Tetrahydrocortisone 3-acetate |
| D,L-Propranolol | Nitroglycerin | Ecgonine methyl ester |
| D,L-Tryptophan | Norethindrone | Methoxyphenamine (except MET test) |
| D,L-Tyrosine | Noscapine | Naloxone |
| Deoxycorticosterone | O-Hydroxyhippuric Acid | Naltrexone |

| | | |
|---|---|---|
| Dextromethorphan | Omeprazole | Tyramine (except AMP test) |
| Diclofenac | | |

**Effect of Urinary pH and Specific Gravity:**
Interference by urinary pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 25% below and 25% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

**B. Method Comparison Study**

The method comparison studies for the device were performed in-house with three operators. Operators ran 80 (40 negative and 40 positive) unaltered urine clinical samples for each drug. The samples were blind labeled and compared to LC-MS/MS results. The results are presented in the table below:

| Drug test | Test Dipcard Result | | Drug-Free | Low Negative by LC-MS/MS (less than -50%) | Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff) | Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%) | High Positive by LC-MS/MS (greater than +50%) |
|---|---|---|---|---|---|---|---|
| AMP (AMP 1000) | Viewer A | + | 0 | 0 | 0 | 7 | 31 |
| | | - | 15 | 8 | 17 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 6 | 31 |
| | | - | 15 | 8 | 17 | 3 | 0 |
| | Viewer C | + | 0 | 0 | 0 | 6 | 31 |
| | | - | 15 | 8 | 17 | 3 | 0 |
| AMP (AMP 500) | Viewer A | + | 0 | 0 | 0 | 8 | 30 |
| | | - | 15 | 12 | 13 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 8 | 30 |
| | | - | 15 | 12 | 13 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 0 | 8 | 30 |
| | | - | 15 | 12 | 13 | 2 | 0 |
| BAR | Viewer A | + | 0 | 0 | 0 | 16 | 22 |
| | | - | 15 | 18 | 7 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 16 | 22 |
| | | - | 15 | 18 | 7 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 0 | 15 | 22 |
| | | - | 15 | 18 | 7 | 3 | 0 |
| BUP | Viewer A | + | 0 | 0 | 2 | 29 | 10 |
| | | - | 15 | 13 | 10 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 2 | 29 | 10 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | - | 15 | 13 | 10 | 1 | 0 |
| | Viewer C | + | 0 | 0 | 1 | 29 | 10 |
| | | - | 15 | 13 | 11 | 1 | 0 |
| BZO | Viewer A | + | 0 | 0 | 1 | 8 | 31 |
| | | - | 15 | 11 | 13 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 2 | 7 | 31 |
| | | - | 15 | 11 | 12 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 1 | 7 | 31 |
| | | - | 15 | 11 | 13 | 2 | 0 |
| COC (COC 300) | Viewer A | + | 0 | 0 | 2 | 11 | 27 |
| | | - | 15 | 13 | 10 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 1 | 11 | 27 |
| | | - | 15 | 13 | 11 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 2 | 11 | 27 |
| | | - | 15 | 13 | 10 | 2 | 0 |
| COC (COC 150) | Viewer A | + | 0 | 0 | 1 | 13 | 25 |
| | | - | 15 | 12 | 12 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 1 | 13 | 25 |
| | | - | 15 | 12 | 12 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 1 | 13 | 25 |
| | | - | 15 | 12 | 12 | 2 | 0 |
| EDDP | Viewer A | + | 0 | 0 | 1 | 11 | 29 |
| | | - | 15 | 6 | 18 | 0 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 11 | 29 |
| | | - | 15 | 6 | 19 | 0 | 0 |
| | Viewer C | + | 0 | 0 | 1 | 11 | 29 |
| | | - | 15 | 6 | 18 | 0 | 0 |
| MDMA | Viewer A | + | 0 | 0 | 1 | 9 | 30 |
| | | - | 15 | 14 | 10 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 9 | 30 |
| | | - | 15 | 14 | 11 | 1 | 0 |
| | Viewer C | + | 0 | 0 | 1 | 9 | 30 |
| | | - | 15 | 14 | 10 | 1 | 0 |
| MET (MET 1000) | Viewer A | + | 0 | 0 | 0 | 8 | 30 |
| | | - | 15 | 8 | 17 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 8 | 30 |
| | | - | 15 | 8 | 17 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 0 | 8 | 30 |
| | | - | 15 | 8 | 17 | 2 | 0 |
| MET (MET 500) | Viewer A | + | 0 | 0 | 0 | 10 | 30 |
| | | - | 15 | 14 | 11 | 0 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 9 | 30 |
| | | - | 15 | 14 | 11 | 1 | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Viewer C | + | 0 | 0 | 0 | 9 | 30 |
| | | - | 15 | 14 | 11 | 1 | 0 |
| OPI (MOP 2000) | Viewer A | + | 0 | 0 | 2 | 9 | 29 |
| | | - | 15 | 9 | 14 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 2 | 9 | 29 |
| | | - | 15 | 9 | 14 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 2 | 9 | 29 |
| | | - | 15 | 9 | 14 | 2 | 0 |
| MOP (MOP 300) | Viewer A | + | 0 | 0 | 2 | 18 | 21 |
| | | - | 15 | 12 | 11 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 2 | 19 | 21 |
| | | - | 15 | 12 | 11 | 0 | 0 |
| | Viewer C | + | 0 | 0 | 2 | 18 | 21 |
| | | - | 15 | 12 | 11 | 1 | 0 |
| MTD | Viewer A | + | 0 | 0 | 2 | 9 | 30 |
| | | - | 15 | 12 | 11 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 2 | 8 | 30 |
| | | - | 15 | 12 | 11 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 2 | 9 | 30 |
| | | - | 15 | 12 | 11 | 1 | 0 |
| OXY | Viewer A | + | 0 | 0 | 2 | 10 | 29 |
| | | - | 15 | 12 | 11 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 2 | 9 | 29 |
| | | - | 15 | 12 | 11 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 2 | 10 | 29 |
| | | - | 15 | 12 | 11 | 1 | 0 |
| PCP | Viewer A | + | 0 | 0 | 0 | 27 | 12 |
| | | - | 15 | 13 | 12 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 28 | 12 |
| | | - | 15 | 13 | 12 | 0 | 0 |
| | Viewer C | + | 0 | 0 | 0 | 27 | 12 |
| | | - | 15 | 13 | 12 | 1 | 0 |
| PPX | Viewer A | + | 0 | 0 | 2 | 11 | 28 |
| | | - | 15 | 13 | 10 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 1 | 12 | 28 |
| | | - | 15 | 13 | 11 | 0 | 0 |
| | Viewer C | + | 0 | 0 | 1 | 10 | 28 |
| | | - | 15 | 13 | 11 | 2 | 0 |
| TCA | Viewer A | + | 0 | 0 | 0 | 6 | 32 |
| | | - | 15 | 13 | 12 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 0 | 6 | 32 |
| | | - | 15 | 13 | 12 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 0 | 6 | 32 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | - | 15 | 13 | 12 | 2 | 0 |
| THC | Viewer A | + | 0 | 0 | 2 | 9 | 30 |
| | | - | 15 | 13 | 10 | 1 | 0 |
| | Viewer B | + | 0 | 0 | 1 | 9 | 30 |
| | | - | 15 | 13 | 11 | 1 | 0 |
| | Viewer C | + | 0 | 0 | 1 | 9 | 30 |
| | | - | 15 | 13 | 11 | 1 | 0 |
| 6-MAM | Viewer A | + | 0 | 0 | 3 | 28 | 10 |
| | | - | 15 | 13 | 9 | 2 | 0 |
| | Viewer B | + | 0 | 0 | 3 | 28 | 10 |
| | | - | 15 | 13 | 9 | 2 | 0 |
| | Viewer C | + | 0 | 0 | 3 | 28 | 10 |
| | | - | 15 | 13 | 9 | 2 | 0 |

Discordant Results are summarized below.

| Drug | Operator | Sample Number | LC/MS/MS Result (ng/mL) | Dochek Result |
|---|---|---|---|---|
| 6-MAM 10 | Viewer A, B, C | 1091 | 9.006 | + |
| | Viewer A, B, C | 1081 | 9.465 | + |
| | Viewer A, B, C | 1053 | 9.967 | + |
| | Viewer A, B, C | 1048 | 10.237 | - |
| | Viewer A, B, C | 1052 | 10.257 | - |
| AMP 1000 | Viewer A, B, C | 0955 | 1014.625 | - |
| | Viewer A, B, C | 0936 | 1056.71 | - |
| | Viewer B, C | 0903 | 1141.794 | - |
| BAR 300 | Viewer A, B, C | 0221 | 302.963 | - |
| | Viewer C | 0238 | 304.207 | - |
| | Viewer A, B, C | 0173 | 312.828 | - |
| BUP 10 | Viewer A, B, C | 0136 | 8.76 | + |
| | Viewer A, B | 0137 | 8.785 | + |
| | Viewer A, B, C | 0141 | 10.761 | - |
| BZO 300 | Viewer B | 0405 | 269.424 | + |
| | Viewer A, B, C | 0428 | 290.449 | + |
| | Viewer B, C | 0422 | 301.512 | - |
| | Viewer A, B, C | 0409 | 301.586 | - |
| COC 300 | Viewer A, B, C | 0632 | 284.614 | + |
| | Viewer A, C | 0602 | 295.071 | + |
| | Viewer A, B, C | 0620 | 307.773 | - |
| | Viewer A, B, C | 0630 | 308.012 | - |
| EDDP 300 | Viewer A, C | 1591 | 296.944 | + |
| MDMA 500 | Viewer A, C | 0762 | 458.975 | + |
| | Viewer A, B, C | 0750 | 565.340 | - |

| | | | | |
|---|---|---|---|---|
| MET 1000 | Viewer A, B, C | 0972 | 1002.105 | - |
| | Viewer A, B, C | 1025 | 1026.596 | - |
| OPI 2000 | Viewer A, B, C | 0817 | 1872.771 | + |
| | Viewer A, B, C | 0855 | 1996.034 | + |
| | Viewer A, B, C | 0879 | 2022.484 | - |
| | Viewer A, B, C | 0880 | 2137.854 | - |
| MTD 300 | Viewer A, B, C | 1159 | 271.186 | + |
| | Viewer A, B, C | 1185 | 273.035 | + |
| | Viewer A, B, C | 1129 | 308.556 | - |
| | Viewer B | 1123 | 324.733 | - |
| OXY 100 | Viewer A, B, C | 0379 | 85.212 | + |
| | Viewer A, B, C | 0375 | 87.649 | + |
| | Viewer B | 0397 | 106.706 | - |
| | Viewer A, B, C | 0340 | 108.7 | - |
| PCP 25 | Viewer A, C | 0053 | 25.901 | - |
| PPX 300 | Viewer A, B, C | 0504 | 285.846 | + |
| | Viewer A | 0487 | 295.988 | + |
| | Viewer A, C | 0536 | 347.008 | - |
| | Viewer C | 0551 | 355.750 | - |
| TCA 1000 | Viewer A, B, C | 0688 | 1,051.49 | - |
| | Viewer A, B, C | 0653 | 1,135.56 | - |
| THC 50 | Viewer A, C | 0300 | 41.179 | + |
| | Viewer A, B | 0317 | 49.391 | + |
| | Viewer A, B, C | 0312 | 55.644 | - |
| AMP 500 | Viewer A, B, C | 1345 | 512.815 | - |
| | Viewer A, B, C | 1297 | 545.751 | - |
| COC 150 | Viewer A, B, C | 1446 | 138.861 | + |
| | Viewer A, B, C | 1512 | 156.470 | - |
| | Viewer A, B, C | 1505 | 162.099 | - |
| MET 500 | Viewer B, C | 1403 | 507.553 | - |
| MOP 300 | Viewer A, B, C | 1279 | 248.796 | + |
| | Viewer A, B, C | 1259 | 249.557 | + |
| | Viewer A, C | 1264 | 308.896 | - |

## C. Lay Person Study

79 male and 61 female tested Dochek® Multi-Drug Urine Test Dipcard Configuration 1; 73 male and 67 female tested Dochek® Multi-Drug Urine Test Dipcard Configuration 2. They had diverse educational and occupational backgrounds and their age range from 21 to > 50. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC-MS/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.

Result of Dochek® Multi-Drug Urine Test Dipcard Configuration 1:

| Drug | Cutoff (ng/mL) | Results | Drug Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| AMP | 1000 | Negative | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Percentage of correct results (%) | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| BAR | 300 | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Percentage of correct results (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| BUP | 10 | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Percentage of correct results (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| BZO | 300 | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Percentage of correct results (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| COC | 300 | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Percentage of correct results (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| EDDP | 300 | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **MDMA** | **500** | **Negative** | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **MET** | **1000** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **OPI** | **2000** | **Negative** | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **MTD** | **300** | **Negative** | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **OXY** | **100** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **PCP** | **25** | **Negative** | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **PPX** | **300** | **Negative** | 20 | 20 | 20 | 20 | 0 | 0 | 0 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Positive** | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **TCA** | **1000** | **Negative** | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **THC** | **50** | **Negative** | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **6-MAM** | **10** | **Negative** | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Result of Dochek® Multi-Drug Urine Test Dipcard Configuration 2:

| **Drug** | **Cutoff (ng/mL)** | **Results** | **Drug Concentration** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **-100% cutoff** | **-75% cutoff** | **-50% cutoff** | **-25% cutoff** | **+25% cutoff** | **+50% cutoff** | **+75% cutoff** |
| **AMP** | **500** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **BAR** | **300** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **BUP** | **10** | **Negative** | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **BZO** | **300** | **Negative** | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **COC** | **150** | **Negative** | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **EDDP** | **300** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **MDMA** | **500** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **MET** | **500** | **Negative** | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| **MOP** | **300** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **MTD** | **300** | **Negative** | 20 | 20 | 20 | 20 | 1 | 0 | 0 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Positive** | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| **OXY** | **100** | **Negative** | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **PCP** | **25** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **PPX** | **300** | **Negative** | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| **TCA** | **1000** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **THC** | **50** | **Negative** | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **6-MAM** | **10** | **Negative** | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | **Positive** | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | **Total** | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | **Percentage of correct results (%)** | 100% | 100% | 100% | 95% | 100% | 100% | 100% |

Participants were given surveys on the ease of understanding the instruction for use. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

## D. Clinical Studies

Not applicable.

## 13. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that Dochek® Multi-Drug Urine Test Dipcard Rx and Dochek® Multi-Drug Urine Test Dipcard are substantially equivalent to the predicate devices.