# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
ASSAY ONLY

## I Background Information:

### A 510(k) Number

K233019

### B Applicant

Hangzhou AllTest Biotech Co.,Ltd

### C Proprietary and Established Names

AllTest Multi-Drug Rapid Test Cup; AllTest Multi-Drug Rapid Test Panel; AllTest Multi-Drug Rapid Test Cup Rx; AllTest Multi-Drug Rapid Test Panel Rx

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| DKZ | Class II | 21 CFR 862.3100 - Amphetamine Test System | TX - Clinical Toxicology |
| NFT | Class II | 21 CFR 862.3100 - Amphetamine test system | TX - Clinical Toxicology |
| DIS | Class II | 21 CFR 862.3150 - Barbiturate test system | TX - Clinical Toxicology |
| JXM | Class II | 21 CFR 862.3170 - Benzodiazepine test system | TX - Clinical Toxicology |
| DJG | Class II | 21 CFR 862.3650 - Opiate test system | TX - Clinical Toxicology |
| PTH | Class II | 21 CFR 862.3150 - Barbiturate test system | TX - Clinical Toxicology |
| DIO | Class II | 21 CFR 862.3250 - Cocaine and cocaine metabolite test system | TX - Clinical Toxicology |

| | | | |
|---|---|---|---|
| DJR | Class II | 21 CFR 862.3620 - Methadone test system | TX - Clinical Toxicology |
| NFV | Class II | 21 CFR 862.3170 - Benzodiazepine test system | TX - Clinical Toxicology |
| LAF | Class II | 21 CFR 862.3610 - Methamphetamine test system | TX - Clinical Toxicology |
| DJC | Class II | 21 CFR 862.3610 - Methamphetamine test system | TX - Clinical Toxicology |
| LDJ | Class II | 21 CFR 862.3870 - Cannabinoid test system | TX - Clinical Toxicology |
| NGL | Class II | 21 CFR 862.3650 - Opiate test system | TX - Clinical Toxicology |
| NFY | Class II | 21 CFR 862.3250 - Cocaine and cocaine metabolite test system | TX - Clinical Toxicology |
| DNK | Class II | 21 CFR 862.3640 - Morphine test system | TX - Clinical Toxicology |
| LCM | Unclassified | | |
| PTG | Class II | 21 CFR 862.3620 - Methadone test system | TX - Clinical Toxicology |
| LFG | Class II | 21 CFR 862.3910 - Tricyclic antidepressant drugs test system | TX - Clinical Toxicology |
| NGG | Class II | 21 CFR 862.3610 - Methamphetamine test system | TX - Clinical Toxicology |
| NFW | Class II | 21 CFR 862.3870 - Cannabinoid test system | TX - Clinical Toxicology |
| NGI | Class II | 21 CFR 862.3640 - Morphine test system | TX - Clinical Toxicology |
| NGM | Unclassified | | |
| QAW | Class II | 21 CFR 862.3910 - Tricyclic antidepressant drugs test system | TX - Clinical Toxicology |

## II Submission/Device Overview:

### A Purpose for Submission:

New Device

**B Measurand:**

Amphetamine, Secobarbital, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Nortriptyline, Oxycodone, and 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine.

**C Type of Test:**

Qualitative lateral flow immunoassay

## III Intended Use/Indications for Use:

**A Intended Use(s):**

See Indications for Use below.

**B Indication(s) for Use:**

AllTest Multi-Drug Rapid Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 500 or 1000 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Benzodiazepines (BZO) | 300 ng/mL |
| Cocaine (COC) | 150 or 300 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methamphetamine (MET) | 500 or 1000 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 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 |
| Nortriptyline (TCA) | 1000 ng/mL |
| Marijuana (THC) | 50 ng/mL |

AllTest Multi-Drug Rapid Test Cup offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, 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 applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

AllTest Multi-Drug Rapid Test Cup Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Calibrator** | **Cut-off (ng/mL)** |
|---|---|---|
| Amphetamine (AMP) | d-Amphetamine | 500 or 1000 |
| Buprenorphine (BUP) | Buprenorphine | 10 |
| Secobarbital (BAR) | Secobarbital | 300 |
| Benzodiazepines (BZO) | Oxazepam | 300 |
| Cocaine (COC) | Benzoylecgonine | 150 or 300 |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 |
| Methamphetamine (MET) | d-Methamphetamine | 500 or 1000 |
| Methylenedioxymethamphetamine (MDMA) | d,l-Methylenedioxymethamphetamine | 500 |
| Morphine (MOP/OPI) | Morphine | 300 or 2000 |
| Methadone (MTD) | Methadone | 300 |
| Oxycodone (OXY) | Oxycodone | 100 |
| Phencyclidine (PCP) | Phencyclidine | 25 |
| Nortriptyline (TCA) | Nortriptyline | 1000 |
| Marijuana (THC) | 11-nor-Δ9-THC-9 COOH | 50 |

AllTest Multi-Drug Rapid Test Cup Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, 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 applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

AllTest Multi-Drug Rapid Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 500 or 1000 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Benzodiazepines (BZO) | 300 ng/mL |
| Cocaine (COC) | 150 or 300 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methamphetamine (MET) | 500 or 1000 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 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 |
| Nortriptyline (TCA) | 1000 ng/mL |
| Marijuana (THC) | 50 ng/mL |

AllTest Multi-Drug Rapid Test Panel offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, 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 applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

AllTest Multi-Drug Rapid Test Panel Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Calibrator** | **Cut-off (ng/mL)** |
|---|---|---|
| Amphetamine (AMP) | d-Amphetamine | 500 or 1000 |

| | | |
|---|---|---|
| Buprenorphine (BUP) | Buprenorphine | 10 |
| Secobarbital (BAR) | Secobarbital | 300 |
| Benzodiazepines (BZO) | Oxazepam | 300 |
| Cocaine (COC) | Benzoylecgonine | 150 or 300 |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 |
| Methamphetamine (MET) | d-Methamphetamine | 500 or 1000 |
| Methylenedioxymethamphetamine (MDMA) | d,l-Methylenedioxymethamphetamine | 500 |
| Morphine (MOP/OPI) | Morphine | 300 or 2000 |
| Methadone (MTD) | Methadone | 300 |
| Oxycodone (OXY) | Oxycodone | 100 |
| Phencyclidine (PCP) | Phencyclidine | 25 |
| Nortriptyline (TCA) | Nortriptyline | 1000 |
| Marijuana (THC) | 11-nor-Δ9-THC-9 COOH | 50 |

AllTest Multi-Drug Rapid Test Panel Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, 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 applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

**C Special Conditions for Use Statement(s):**

Rx and OTC

**D Special Instrument Requirements:**

Not Applicable.

## IV Device/System Characteristics:

**A Device Description:**

The AllTest Multi-Drug Rapid Test Cup and AllTest Multi-Drug Rapid Test Panel (Rx and OTC) are lateral flow-based, competitive immunochromatographic assays for the detection of Amphetamine, Secobarbital, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Nortriptyline, Oxycodone, and 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine. The devices are intended for use as the first step in a two-step process to provide consumers with information concerning

the presence or absence of the above stated drugs in a urine sample. Information regarding confirmatory testing – the second step in the process is described in the instructions for use.

**REAGENTS AND MATERIALS SUPPLIED**

(25 Tests per Kit)

- 25 Test Cups or Panels with desiccant in a sealed foil pouch
- 1 Instruction for use

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timer
- Specimen Collection Container

**B Principle of Operation:**

The AllTest Multi-Drug Rapid Test Cup/Panel tests are rapid tests for the qualitative detection of target drug or drug metabolites 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 cutoff 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.

## V Substantial Equivalence Information:

**A Predicate Device Name(s):**

Single and Multi-Drug Rapid Test Panel With Adulteration (Urine) Single and Multi-Drug Rapid Test Panel (Urine) Single and Multi-Drug Rapid Test Cup With Adulteration (Urine) Single and Multi-Drug Rapid Test Cup (Urine) Single Drug Rapid Test Dipstick (Urine) Single and Multi-Drug Home Rapid Test Panel (Urine) Single and Multi-Drug Home Rapid Test Cup (Urine) Single Drug Home Rapid Test Dipstick (Urine)

**B Predicate 510(k) Number(s):**

K182738

**C Comparison with Predicate(s):**

| **Device & Predicate Device(s):** | K233019 | K182738 |
|---|---|---|
| Device Trade Name | AllTest Multi-Drug Rapid Test Cup<br>AllTest Multi-Drug Rapid Test Cup Rx<br>AllTest Multi-Drug Rapid Test Panel<br>AllTest Multi-Drug Rapid Test Panel Rx | Single and Multi-Drug Rapid Test Panel With Adulteration (Urine)<br>Single and Multi-Drug Rapid Test Panel (Urine)<br>Single and Multi-Drug Rapid Test Cup With Adulteration (Urine)<br>Single and Multi-Drug Rapid Test Cup (Urine)<br>Single Drug Rapid Test Dipstick (Urine)<br>Single and Multi-Drug Home Rapid Test Panel (Urine)<br>Single and Multi-Drug Home Rapid Test Cup (Urine)<br>Single Drug Home Rapid Test Dipstick (Urine) |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | For the qualitative determination of drugs and drug metabolites in human urine. | Same |
| Specimen Type | Human Urine | Same |
| Methodology | Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry. | Same |
| Configurations | Panel and Cup | Same |
| Intended Use | Rx and OTC | Same |
| **General Device Characteristic Differences** | | |

| | | |
|---|---|---|
| **Calibrator and Cutoff Values** | Amphetamine (AMP): 500 or 1000 ng/ml<br>Benzodiazepines (BZO):300 ng/ml<br>Cocaine (COC): 150 or 300 ng/ml<br>11-Nor-Δ9-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml<br>Methamphetamine (MET): 500 or 1000 ng/ml<br>Morphine (MOP/OPI): 300 or 2000 ng/mL<br>Oxycodone(OXY) : 100 ng/ml<br>Secobarbital (BAR): 300 ng/ml<br>Methadone (MTD): 300 ng/ml<br>Buprenorphine (BUP): 10 ng/ml<br>D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml<br>Phencyclidine (PCP): 25 ng/ml<br>Nortriptyline (TCA): 1000 ng/ml<br>2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 300 ng/ml | Same except<br>AMP 500 ng/ml only<br>MET 500 ng/ml only<br>COC 150 ng/ml only |

## VI Standards/Guidance Documents Referenced:

None.

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. 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% cutoff and +100% cutoff using 3 lots of the test cup and 3 lots of the test panel. These samples were prepared by spiking drug in negative urine 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 5 replicates per day for 5 days per device in a randomized order. The results obtained for Amphetamine 1000, Cocaine 300, and Methamphetamine 1000 are summarized in the following tables. The rest of the data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Benzodiazepines, EDDP, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana were reported in K182738.

**AMP 1000 Cup**

| **Concen. by LC/MS (ng/mL)** / **Lot Number** | **-100% Cutoff** | **-75% Cutoff** | **-50% Cutoff** | **-25% Cutoff** | **Cutoff** | **Cutoff +25%** | **Cutoff +50%** | **Cutoff +75%** | **Cutoff +100%** |
|---|---|---|---|---|---|---|---|---|---|
| **Lot 1** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 19+/6- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 2** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 19+/6- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 3** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |

**AMP 1000 Panel**

| **Concen. by LC/MS (ng/mL)** / **Lot Number** | **-100% Cutoff** | **-75% Cutoff** | **-50% Cutoff** | **-25% Cutoff** | **Cutoff** | **Cutoff +25%** | **Cutoff +50%** | **Cutoff +75%** | **Cutoff +100%** |
|---|---|---|---|---|---|---|---|---|---|
| **Lot 1** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 2** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 19+/6- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 3** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 21+/4- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |

**COC 300 Cup**

| **Concen. by LC/MS (ng/mL)** | **-100% Cutoff** | **-75% Cutoff** | **-50% Cutoff** | **-25% Cutoff** | **Cutoff** | **Cutoff +25%** | **Cutoff +50%** | **Cutoff +75%** | **Cutoff +100%** |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

| Lot Number | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Lot 1** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 2** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 19+/6- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 3** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 21+/4- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |

**COC 300 Panel**

| Concen. by LC/MS (ng/mL) / Lot Number | -100% Cutoff | -75% Cutoff | -50% Cutoff | -25% Cutoff | Cutoff | Cutoff +25% | Cutoff +50% | Cutoff +75% | Cutoff +100% |
|---|---|---|---|---|---|---|---|---|---|
| **Lot 1** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 2** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 3** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |

**MET 1000 Cup**

| Concen. by LC/MS (ng/mL) / Lot Number | -100% Cutoff | -75% Cutoff | -50% Cutoff | -25% Cutoff | Cutoff | Cutoff +25% | Cutoff +50% | Cutoff +75% | Cutoff +100% |
|---|---|---|---|---|---|---|---|---|---|
| **Lot 1** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 19+/6- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 2** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 19+/6- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 3** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |

**MET 1000 Panel**

| Concen. by LC/MS (ng/mL) / Lot Number | -100% Cutoff | -75% Cutoff | -50% Cutoff | -25% Cutoff | Cutoff | Cutoff +25% | Cutoff +50% | Cutoff +75% | Cutoff +100% |
|---|---|---|---|---|---|---|---|---|---|

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Lot 1** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 20+/5- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 2** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 21+/4- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |
| **Lot 3** | 25-/0+ | 25-/0+ | 25-/0+ | 25-/0+ | 21+/4- | 25+/0- | 25+/0- | 25+/0- | 25+/0- |

2. Linearity:

   Not Applicable.

3. Analytical Specificity/Interference:

   **Interfering Substances**

   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 all analyte cut-off levels in the test. These urine samples were tested using three lots of each device format by twelve operators (six for the cup device and six for the panel device). Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables. No differences were observed for the different device formats.

| | | |
|---|---|---|
| Acetylsalicylic Acid | 5, 5-Diphenylhydantoin | 19-Norethindrone |
| Albumin (100mg/dL) | Erythromycin | Noscapine |
| Amoxicillin | Estradiol | Octopamine |
| Ampicillin | Estrone | Papaverine |
| Aspartame | Ethanol (1%) | Penicillin-G |
| Aspirin | Fenofibrate | Perphenazine |
| Atropine | Fentanyl | Phenelzine |
| Baclofen | Fotemustine | Phenylethylamine |
| Benzocaine | Furosemide | Promazine |
| Benzoic Acid | Gemfibrozil | Promethazine |
| Bilirubin | Gentisic acid | Pyridoxine |
| Carisoprodol | Glucose | Pyrilamine |
| Chloramphenicol | Guaiacol glyceryl ether | Pyrogallol |
| Chlordiazepoxide | Hemoglobin | Quinine |
| (+)-Chlorpheniramine | Hydralazine | Quinolinic Acid |
| Chlorpromazine | Hydrocortisone | R-(-)-Apomorphine |
| Cholesterol | 3-Hydroxytyramine | Ranitidine |
| Clonidine | (+/-)-Isoproterenol | Salicylic Acid |
| Cortisone | Ketamine | Sulindac |
| (-)-Cotinine | L-Ascorbic Acid | Tetracycline |
| Creatine Hydrate | Meprobamate | Tetrahydrozoline |
| Creatinine | Methylphenidate | Thiamine |
| Cyclodextrin | Nalidixic Acid | Thioridazine |
| d,l-Propranolol | Naltrexone | Tramadol |
| Deoxycorticosterone | (+)-Naproxen | Trifluoperazine |
| Dextromethorphan | Niacinamide | Tryptamine |
| Diclofenac | Nicotinic Acid | Uric Acid |

| | | |
|---|---|---|
| 4-Dimethyl-aminoantipyrine | Nifedipine | Zomepirac sodium salt |

**Cross Reactivity**

To test specificity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three lots of each device. The lowest concentrations that caused a positive result for each compound are listed below for Amphetamine 1000, Cocaine 300, and Methamphetamine 1000. No differences were observed for different device format.
The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Benzodiazepines, Morphine, Methadone, Oxycodone, Phencyclidine, EDDP, Nortriptyline and Marijuana were reported in K182738.

| **AMP 1000 (Cutoff=1000 ng/mL)** | **Result Positive at (ng/ml)** | **%Cross-Reactivity** |
|---|---|---|
| d-Amphetamine | 1000 | 100% |
| Methylenedioxyethylamphetamine (MDEA) | >100000 | <1% |
| d,l-Methamphetamine | >100000 | <1% |
| Phenylephrine | >100000 | <1% |
| d-Methamphetamine | >100000 | <1% |
| l-Methamphetamine | >100000 | <1% |
| d,l - Methylenedioxy methamphetamine | >100000 | <1% |
| l-Amphetamine | 1000 | 100% |
| Ephedrine | >100000 | <1% |
| Pseudoephedrine | >100000 | <1% |
| d, l-Amphetamine | 1000 | 100% |
| d,l-3,4-Methylenedioxyamphetamine (MDA) | 50 | 2000% |
| Phentermine | 1000 | 100% |

| **COC 300 (Cutoff=300 ng/mL)** | **Result Positive at (ng/ml)** | **%Cross-Reactivity** |
|---|---|---|
| Benzoylecgonine | 300 | 100% |
| Cocaine | 250 | 120% |
| Cocaethylene | 500 | 60% |
| Ecgonine | >100000 | <0.3% |
| Norcocaine | >100000 | <0.3% |

| **MET 1000 (Cutoff=1000 ng/mL)** | **Result Positive at (ng/ml)** | **%Cross-Reactivity** |
|---|---|---|
| d-Methamphetamine | 1000 | 100% |
| l -Methamphetamine | 25000 | 4% |
| d,l-Amphetamine | 500 | 200% |

| | | |
|---|---|---|
| Phentermine | >100000 | <1% |
| d,l-Methamphetamine | 500 | 200% |
| d-Amphetamine | >100000 | <1% |
| l-Amphetamine | >100000 | <1% |
| Ephedrine | >100000 | <1% |
| Phenylephrine | >100000 | <1% |
| Pseudoephedrine | >100000 | <1% |
| 3,4- Methylenedioxy methamphetamine (MDMA) | 2500 | 40% |
| d,l- Methylenedioxy ethylamphetamine (MDEA) | 12500 | 8.0% |
| d,l-3,4-Methylenedioxyamphetamine (MDA) | >100000 | <1% |

**Effect of Urine Specific Gravity and Urine pH**

Effect of urine density and pH data were reported only for Amphetamine 1000, Cocaine 300 and Methamphetamine 1000. The rest of the data were reported in the cleared AllTest submission of K182738.

The effect of pH was evaluated by preparing samples with test drug analytes at +/-25% of the cutoff for all devices and adjusting the pH to 4.00 to 9.00, in increments of 1 pH unit. There were no interferences observed.

The effect of specific gravity was evaluated by preparing samples with test drug analytes at +/-25% of the cutoff for all devices and adjusting the specific gravity to 1.000, 1.005, 1.008, 1.011, 1.013, 1.016, 1.022, 1.025, 1.027, 1.029, 1.033, 1.035. There were no interferences observed.

4. Assay Reportable Range:

   Not Applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   All drug calibrators of the device are traceable to available commercial reference materials.

6. Detection Limit:

   See precision data in Section VII.A.1., above, for assay performance around the claimed cutoff concentrations.

7. Assay Cutoff:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section VII.A.1., above.

## B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies were performed at the manufacturer's site using three operators for each device format (cup and panel). Operators tested a minimum of 40 unaltered positive and 40 unaltered negative 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 Amphetamine 1000, Cocaine 300, and Methamphetamine 1000. The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Benzodiazepines, Morphine, Methadone, Oxycodone, Phencyclidine, EDDP, Nortriptyline and Marijuana were reported in K182738.

**AMP Cup**

| AllTest Multi-Drug Test 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 | 13 | 26 |
| | Negative | 12 | 12 | 15 | 1 | 0 |
| Viewer B | Positive | 0 | 0 | 0 | 13 | 26 |
| | Negative | 12 | 12 | 16 | 1 | 0 |
| Viewer C | Positive | 0 | 0 | 1 | 14 | 26 |
| | Negative | 12 | 12 | 15 | 0 | 0 |

Discordant Results

| Viewer | Sample Number | LC/MS Result | Viewer Results |
|---|---|---|---|
| **Viewer A** | SN165 | 896.471 | + |
| **Viewer A** | SN175 | 1070.815 | - |
| **Viewer B** | SN044 | 1149.522 | - |
| **Viewer C** | SN128 | 838.956 | + |

**AMP Panel**

| AllTest Multi-Drug Test Panel | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cutoff) | Near Cutoff Positive by LC/MS (Between the cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Viewer A | Positive | 0 | 0 | 0 | 13 | 26 |
| | Negative | 12 | 12 | 16 | 1 | 0 |
| Viewer B | Positive | 0 | 0 | 1 | 14 | 26 |
| | Negative | 12 | 12 | 15 | 0 | 0 |
| Viewer C | Positive | 0 | 0 | 2 | 13 | 26 |
| | Negative | 12 | 12 | 14 | 1 | 0 |

Discordant Results

| Viewer | Sample Number | LC/MS Result | Viewer Results |
|---|---|---|---|
| **Viewer A** | SN044 | 1149.522 | - |
| **Viewer B** | SN062 | 833.996 | + |
| **Viewer C** | SN036 | 922.995 | + |
| **Viewer C** | SN120 | 987.795 | + |
| **Viewer C** | SN150 | 1181.731 | - |

**COC Cup**

| AllTest Multi-Drug Test Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cutoff) | Near Cutoff Positive by LC/MS (Between the cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Viewer A | Positive | 0 | 0 | 0 | 9 | 30 |
| | Negative | 12 | 10 | 18 | 1 | 0 |
| Viewer B | Positive | 0 | 0 | 1 | 10 | 30 |
| | Negative | 12 | 10 | 17 | 0 | 0 |
| Viewer C | Positive | 0 | 0 | 1 | 10 | 30 |
| | Negative | 12 | 10 | 17 | 0 | 0 |

Discordant Results

| Viewer | Sample Number | LC/MS Result | Viewer Results |
|---|---|---|---|
| **Viewer A** | SN174 | 324.6 | - |
| **Viewer B** | SN070 | 297.0 | + |
| **Viewer C** | SN079 | 297.7 | + |

**COC Panel**

| AllTest Multi-Drug Test Panel | | 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 | 8 | 30 |
| | Negative | 12 | 10 | 17 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 1 | 10 | 30 |
| | Negative | 12 | 10 | 17 | 0 | 0 |
| Viewer C | Positive | 0 | 0 | 0 | 8 | 30 |
| | Negative | 12 | 10 | 18 | 2 | 0 |

Discordant Results

| Viewer | Sample Number | LC/MS Result | Viewer Results |
|---|---|---|---|
| **Viewer A** | SN079 | 297.79 | + |
| **Viewer A** | SN142 | 352.11 | - |
| **Viewer A** | SN174 | 324.69 | - |
| **Viewer B** | SN012 | 292.74 | + |
| **Viewer C** | SN084 | 312.95 | - |
| **Viewer C** | SN142 | 352.11 | - |

**MET Cup**

| AllTest Multi-Drug Test 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 | 10 | 29 |
| | Negative | 12 | 11 | 16 | 1 | 0 |
| Viewer B | Positive | 0 | 0 | 0 | 10 | 29 |

| AllTest Multi-Drug Test 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%) |
|---|---|---|---|---|---|---|
| | Negative | 12 | 11 | 17 | 1 | 0 |
| Viewer C | Positive | 0 | 0 | 2 | 10 | 29 |
| | Negative | 12 | 11 | 15 | 1 | 0 |

Discordant Results

| Viewer | Sample Number | LC/MS Result | Viewer Results |
|---|---|---|---|
| **Viewer A** | SN108 | 974.577 | + |
| **Viewer A** | SN043 | 1194.980 | - |
| **Viewer B** | SN043 | 1194.980 | - |
| **Viewer C** | SN054 | 919.834 | + |
| **Viewer C** | SN188 | 841.261 | + |
| **Viewer C** | SN197 | 1167.315 | - |

**MET Panel**

| AllTest Multi-Drug Test Panel | | 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 | 9 | 29 |
| | Negative | 12 | 11 | 16 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 1 | 10 | 29 |
| | Negative | 12 | 11 | 16 | 1 | 0 |
| Viewer C | Positive | 0 | 0 | 0 | 10 | 29 |
| | Negative | 12 | 11 | 17 | 1 | 0 |

Discordant Results

| Viewer | Sample Number | LC/MS Result | Viewer Results |
|---|---|---|---|
| **Viewer A** | SN159 | 882.244 | + |
| **Viewer A** | SN043 | 1194.980 | - |
| **Viewer A** | SN186 | 1138.254 | - |
| **Viewer B** | SN159 | 882.244 | + |

| | | | |
|---|---|---|---|
| **Viewer B** | SN186 | 1138.254 | - |
| **Viewer C** | SN197 | 1167.315 | - |

**Lay User Study**

A lay user study was performed at three intended user sites by 560 lay users. Each lay user tested only one sample (140 tested the low cutoff test cup, 140 tested the low cutoff test panel, 140 tested the high cutoff test cup, and 140 tested the high cutoff test panel). The lay users had diverse educational and professional backgrounds and ranged in age from 20 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 format was tested. Results are shown below.

**Results for Low Cutoff Cup**

| **Drug** | **Cutoff (ng/mL)** | **Results** | **Concentration** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **-100% cutoff** | **-75% cutoff** | **-50% cutoff** | **-25% cutoff** | **+25% cutoff** | **+50% cutoff** | **+75% cutoff** |
| AMP | 500 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| BAR | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| BZO | 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 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 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 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| COC | 150 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| | | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| EDDP | 300 | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| MDMA | 500 | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| MET | 500 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| | | (%) | | | | | | | |
| MOP | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| MTD | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| OXY | 100 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| PCP | 25 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| TCA | 1000 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| THC | 50 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |

**Results for High Cutoff Cup**

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| AMP | 1000 | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| BAR | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| BZO | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| BUP | 10 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| COC | 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 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| EDDP | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| MDMA | 500 | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| MET | 1000 | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| OPI | 2000 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 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 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| OXY | 100 | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| PCP | 25 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| TCA | 1000 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| THC | 50 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |

**Results for Low Cutoff Panel**

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| AMP | 500 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| BAR | 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 |

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| BZO | 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 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| BUP | 10 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| COC | 150 | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| EDDP | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| MDMA | 500 | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| MET | 500 | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| MOP | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| MTD | 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 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| | | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| OXY | 100 | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| PCP | 25 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| TCA | 1000 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| THC | 50 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |

**Results for High Cutoff Panel**

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

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| COC | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| EDDP | 300 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| MDMA | 500 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| MET | 1000 | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| OPI | 2000 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| MTD | 300 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| OXY | 100 | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| PCP | 25 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| TCA | 1000 | Negative | 20 | 20 | 20 | 18 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **-100% cutoff** | **-75% cutoff** | **-50% cutoff** | **-25% cutoff** | **+25% cutoff** | **+50% cutoff** | **+75% cutoff** |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 90% | 100% | 100% |
| THC | 50 | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 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.

2. Matrix Comparison:

Not Applicable.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not Applicable.

2. Clinical Specificity:

Not Applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not Applicable.

**D Clinical Cutoff:**

Not Applicable.

**E Expected Values/Reference Range:**

Not Applicable.

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.