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

## I Background Information:

### A 510(k) Number

K260065

### B Applicant

Guangzhou Wondfo Biotech Co., Ltd.

### C Proprietary and Established Names

SAFElife™ T-Dip Multi-Drug Urine Test Panel
SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| NFT | Class II | 21 CFR 862.3100 | Toxicology (91) |
| NGL | Class II | 21 CFR 862.3650 | Toxicology (91) |
| PTH | Class II | 21 CFR 862.3150 | Toxicology (91) |
| NFV | Class II | 21 CFR 862.3170 | Toxicology (91) |
| NFY | Class II | 21 CFR 862.3250 | Toxicology (91) |
| PTG | Class II | 21 CFR 862.3620 | Toxicology (91) |
| NGG | Class II | 21 CFR 862.3610 | Toxicology (91) |
| LCM | Class II | Unclassified | Toxicology (91) |
| QBF | Class II | 21 CFR 862.3700 | Toxicology (91) |
| QAW | Class II | 21 CFR 862.3910 | Toxicology (91) |
| NFW | Class II | 21 CFR 862.3870 | Toxicology (91) |

## II Submission/Device Overview:

### A Purpose for Submission:

Addition of new analytes to a previously cleared device

**B Measurand:**

6-Monoacetylmorphine
Amphetamine
Secobarbital
Buprenorphine
Oxazepam
Benzoylecgonine
2-ethylidene-1,5 dimethyl-3,3-diphenylpyrrolidine (EDDP)
Fentanyl
3,4 Methylenedioxymethamphetamine
D(+)-Methamphetamine
Morphine
Methadone
Norfentanyl
Oxycodone
Phencyclidine
d-Propoxyphene
Nortriptyline
11-nor-Δ9-THC-9-COOH
Tramadol

**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:**

SAFElife™ T Dip Multi Drug Urine Test Panel
SAFElife™ T Dip Multi Drug Urine Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of 6-Monoacetylmorphine, Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Fentanyl, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Opiates, Methadone, Norfentanyl, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Cannabinoids and Tramadol in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Cutoff Level** |
|---|---|
| 6-Monoacetylmorphine (6-MAM) | 10 ng/mL |
| Amphetamine (AMP) | 1000 ng/mL or 500 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |

| | |
|---|---|
| Secobarbital (BAR) | 300 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 300 ng/mL or 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Fentanyl (FTY) | 1 ng/mL |
| Methamphetamine (MET/mAMP) | 1000 ng/mL or 500 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Morphine (MOP) | 300 ng/mL |
| Opiates (OPI) | 2000 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Norfentanyl (NFTY) | 5 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 or 20 ng/mL |
| Tramadol (TRA) | 100 ng/mL |

SAFElife™ T-Dip Multi-Drug Urine Test Panel offers any combinations from 1 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use.
The tests may yield positive results for the prescription drugs Buprenorphine, Fentanyl, Nortriptyline, Oxazepam, Secobarbital, Oxycodone and Tramadol 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. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the recommended confirmatory method.

SAFElife™ T Dip Multi Drug Urine Test Panel Dx

SAFElife™ T Dip Multi Drug Urine Test Panel Dx is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of 6 Monoacetylmorphine, Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2 ethylidene 1,5 dimethyl 3,3 diphenylpyrrolidine (EDDP), Fentanyl, Methylenedioxymethamphetamine, Methamphetamine, Morphine, Opiates, Methadone, Norfentanyl, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Cannabinoids and Tramadol in human urine with below cutoff concentrations and approximate detection time:

| **Drug (Identifier)** | **Calibrator** | **Cut-off** |
|---|---|---|
| 6-Monoacetylmorphine (6-MAM) | 6-Monoacetylmorphine | 10 ng/mL |
| Amphetamine (AMP500) | d-Amphetamine | 500 ng/mL |
| Amphetamine (AMP1000) | d-Amphetamine | 1000 ng/mL |
| Secobarbital (BAR) | Secobarbital | 300 ng/mL |
| Buprenorphine (BUP) | Buprenorphine | 10 ng/mL |
| Oxazepam (BZO) | Oxazepam | 300 ng/mL |

| | | |
|---|---|---|
| Cocaine (COC150) | Benzoylecgonine | 150 ng/mL |
| Cocaine (COC300) | Benzoylecgonine | 300 ng/mL |
| 2-ethylidene-1,5 dimethyl-3, 3-diphenylpyrrolidine (EDDP) | 2-ethylidene-1,5 dimethyl-3, 3-diphenylpyrrolidine | 300 ng/mL |
| Fentanyl (FTY) | Fentanyl | 1 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 3,4-Methylenedioxymethamphetamine | 500 ng/mL |
| Methamphetamine (MET500/mAMP500) | D (+)-Methamphetamine | 500 ng/mL |
| Methamphetamine (MET1000/mAMP1000) | D (+)-Methamphetamine | 1000 ng/mL |
| Morphine (MOP300) | Morphine | 300 ng/mL |
| Opiates (OPI2000) | Morphine | 2000 ng/mL |
| Methadone (MTD) | Methadone | 300 ng/mL |
| Norfentanyl (NFTY) | Norfentanyl | 5 ng/mL |
| Oxycodone (OXY) | Oxycodone | 100 ng/mL |
| Phencyclidine (PCP) | Phencyclidine | 25 ng/mL |
| Propoxyphene (PPX) | d-Propoxyphene | 300 ng/mL |
| Nortriptyline (TCA) | Nortriptyline | 1000 ng/mL |
| Cannabinoids (THC20) | 11-nor-Δ9-THC-9-COOH | 20 ng/mL |
| Cannabinoids (THC50) | 11-nor-Δ9-THC-9-COOH | 50 ng/mL |
| Tramadol (TRA) | Tramadol | 100 ng/mL |

SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx offers any combinations from 1 to 15 drugs of abuse tests with or without on-board adulteration/specimen validity test (SVT) but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use.
The tests may yield positive results for the prescription drugs Buprenorphine, Fentanyl, Nortriptyline, Oxazepam, Secobarbital, Oxycodone and Tramadol 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. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the recommended confirmatory method.

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

**D Special Instrument Requirements:**

N/A

## IV Device/System Characteristics:

**A Device Description:**

SAFElife™ T-Dip Multi-Drug Urine Test Panel and SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Opiates, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Cannabinoids, 6-Monoacetylmorphine, Fentanyl, Norfentanyl, and Tramadol in human urine. Each SAFElife™ T-Dip Multi-Drug Urine Test Panel or SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx device consists of a test panel and a package insert. Each test panel is sealed with one desiccant in an aluminum pouch.

**B Principle of Operation:**

SAFElife™ T-Dip Multi-Drug Urine Test Panel and SAFElife™ T-Dip Multi Drug Urine Test Panel Dx are competitive immunochromatographic assays that are used to screen for the presence of drugs of abuse in urine. During testing, the urine specimen mixes with the drug specific monoclonal antibody conjugate, and flows across the membrane. When sample drug levels are zero or below the target cutoff, drug monoclonal antibody conjugate binds to the respective drug protein conjugate immobilized in the Test Region (T). This produces a colored band in the Test Region (T) that, regardless of its intensity, indicates a negative result. When drug concentration in the sample is at or above the target cutoff, the 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). This prevents the development of a colored band in the Test Region (T), indicating a potentially positive result.

## V Substantial Equivalence Information:

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

Wondfo T-Dip® Multi-Drug Urine Test Panel
Wondfo T-Dip® Multi-Drug Urine Test Panel Rx

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

K202567

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

| **Device & Predicate Device(s):** | K260065 | Predicate (K202567) |
|---|---|---|
| Device Trade Name | SAFElife™ T-Dip Multi-Drug Urine Test Panel<br>SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx | Wondfo T-Dip® Multi-Drug Urine Test Panel<br>Wondfo T-Dip® Multi-Drug Urine |

| | | | Test Panel Rx |
|---|---|---|---|
| **General Device Characteristic Similarities** | | | |
| Intended Use/Indications For Use | For the qualitative determination of drugs of abuse in human urine | | Same |
| Methodology | Competitive binding, lateral flow immunochromatographic assay | | Same |
| Type of Test | Qualitative | | Same |
| Specimen Type | Human urine | | Same |
| Target Drug and Cut Off Values | Target Drugs | Cutoff | Same except that no FTY1, NFTY5, THC20, and TRA100 |
| | Amphetamine (AMP) | 1000 ng/mL or 500 ng/mL | |
| | Buprenorphine (BUP) | 10 ng/mL | |
| | Secobarbital (BAR) | 300 ng/mL | |
| | Oxazepam (BZO) | 300 ng/mL | |
| | Cocaine (COC) | 300 ng/mL or 150 ng/mL | |
| | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL | |
| | Methamphetamine (MET/mAMP) | 1000 ng/mL or 500 ng/mL | |
| | Methylenedioxymethamphetamine (MDMA) | 500 ng/mL | |
| | Morphine (MOP) | 300 ng/mL | |
| | Opiates (OPI) | 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 | 10 ng/mL | |

| | | | |
|---|---|---|---|
| | (6-MAM) | | |
| | Fentanyl (FTY) | 1 ng/mL | |
| | Norfentanyl (NFTY) | 5 ng/mL | |
| | Cannabinoids (THC) | 20 ng/mL | |
| | Tramadol (TRA) | 100 ng/mL | |
| **General Device Characteristic Differences** | | | |
| Target Drug and Cut Off Values | See above | | No FTY1, NFTY5, THC20, and TRA100 |

## VI Standards/Guidance Documents Referenced:

N/A

## 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% cut off, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff, +75% cutoff and +100% cutoff for 6-Monoacetylmorphine (6-MAM10), Fentanyl (FTY1), Norfentanyl (NFTY5), Cannabinoids (THC20), and Tramadol (TRA100). Samples with concentration of -100% cutoff were drug-free urine samples. Other samples were prepared by spiking target drug in drug-free urine samples. Each drug concentration was confirmed by LC/MS or GC/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test panels. The results of a representative lot are summarized in the following tables. Precision results for AMP500/1000, BAR300, BUP10, BZO300, COC150/300, EDDP300, MDMA500, MET500/MET1000, MOP300, MTD300, OPI2000, OXY100, PCP25, PPX300, TCA1000 and THC50 were previously reviewed under K202567.

| Drug | Lot Number | +100% cutoff | +75% cutoff | +50% cutoff | +25% cutoff | Cutoff | -25% cutoff | -50% cutoff | -75% cutoff | -100% cut-off |
|---|---|---|---|---|---|---|---|---|---|---|
| **6AM 10** | **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 25-/25+ | 1-/49+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 26-/24+ | 2-/48+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 48-/2+ | 25-/25+ | 2-/48+ | 0-/50+ | 0-/50+ | 0-/50+ |
| **FTY1** | **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 24-/26+ | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 48-/2+ | 25-/25+ | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 27-/23+ | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 48-/2+ | 25-/25+ | 1-/49+ | 0-/50+ | 0-/50+ | 0-/50+ |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **NFTY 5** | **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 24-/26+ | 1-/49+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 26-/24+ | 2-/48+ | 0-/50+ | 0-/50+ | 0-/50+ |
| **THC20** | **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 48-/2+ | 25-/25+ | 2-/48+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 27-/23+ | 1-/49+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 24-/26+ | 1-/49+ | 0-/50+ | 0-/50+ | 0-/50+ |
| **TRA 100** | **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 25-/25+ | 1-/49+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 49-/1+ | 26-/24+ | 2-/48+ | 0-/50+ | 0-/50+ | 0-/50+ |
| | **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 48-/2+ | 25-/25+ | 2-/48+ | 0-/50+ | 0-/50+ | 0-/50+ |

2. Linearity:

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

3. Analytical Specificity/Interference:

Cross-reactivity/Interference of AMP500/1000, BAR300, BUP10, BZO300, COC150/300, EDDP300, MDMA500, MET500/MET1000, MOP300, MTD300, OPI2000, OXY100, PCP25, PPX300, TCA1000 and THC50 were previously reviewed under K202567. In this submission, 6-Monoacetylmorphine (6-MAM10), Fentanyl (FTY1), Norfentanyl (NFTY5), Cannabinoids (THC20), and Tramadol (TRA100) study data are summarized and presented below.

Cross-reactivity:
To test the specificity, drug metabolites and other components that are likely to cross-react in urine samples were spiked into drug-free urine. 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; compounds that did not yield a positive result at the highest concentration tested have relative cross reactivity results. The results obtained are summarized in tables below.

| **Drug/Cutoff** | **Compound** | **Minimum concentration required to obtain a positive result (ng/mL)** | **% Cross-reactivity** |
|---|---|---|---|
| 6-MAM | Heroin | 60 | 16.7% |
| | Morphine | 75000 | 0.01% |
| | Normorphine | 150000 | Not detected |
| | Nalorphine HCl | 150000 | Not detected |
| | Hydrocodone | 150000 | Not detected |
| | Hydromorphone | 150000 | Not detected |
| | Chlordiazepoxide | 150000 | Not detected |
| | Clobazam | 150000 | Not detected |
| | D-Amphetamine | 150000 | Not detected |
| | (±)-Amphetamine | 150000 | Not detected |

| | | | |
|---|---|---|---|
| | Levorphanol tartrate | 150000 | Not detected |
| | Codeine | 150000 | Not detected |
| | Ethylmorphine | 150000 | Not detected |
| | Morphine3-β-D-glucuronide | 150000 | Not detected |
| | Norcodeine | 150000 | Not detected |
| | Oxycodone | 150000 | Not detected |
| | Oxymorphone | 150000 | Not detected |
| | Procaine hydrochloride | 150000 | Not detected |
| | Thebaine | 150000 | Not detected |
| | 6-Acetylcodeine | 150000 | Not detected |
| | Buprenorphine | 150000 | Not detected |
| | Dihydrocodeine | 150000 | Not detected |
| | Dextromethorphan | 150000 | Not detected |
| | Imipramine hydrochloride | 150000 | Not detected |
| | Meperidine | 150000 | Not detected |
| | (±)-Methadone | 150000 | Not detected |
| | Mitragynine(kratom) | 150000 | Not detected |
| | Morphine-6-β-D-glucuonide | 150000 | Not detected |
| | Naloxone hydrochloride | 150000 | Not detected |
| | Naltrexone hydrochloride | 150000 | Not detected |
| | Naproxen | 150000 | Not detected |
| | Norbuprenorphine | 150000 | Not detected |
| | Norbuprenorphine glucuronide | 150000 | Not detected |
| | Noroxycodone HCL | 150000 | Not detected |
| | Noroxymorphone HCL | 150000 | Not detected |
| | (+)-Norpropoxyphene maleate | 150000 | Not detected |
| | Oxymorphone-3β-D-glucuronide | 150000 | Not detected |
| | Tapentadol HCl | 150000 | Not detected |
| | Tramadol | 150000 | Not detected |
| FTY1 | Acetyl fentanyl | 16 | 6.25% |
| | Acrylfentanyl | 1 | 100.00% |
| | ω-1-Hydroxyfentanyl | 20,000 | 0.005% |
| | Isobutyryl fentanyl | 1 | 100.00% |
| | Ocfentanil | 2.3 | 43.48% |
| | Butyryl fentanyl | 2 | 50.00% |
| | Furanyl fentanyl | 1 | 100.00% |
| | Valeryl fentanyl | 2.5 | 40.00% |
| | (±) β-hydroxythiofentanyl | 2.5 | 40.00% |
| | 4-Fluoro-isobutyrylfentanyl | 3 | 33.33% |

| | | | |
|---|---|---|---|
| | Para-fluorobutyryl fentanyl | 4 | 25.00% |
| | Para-fluoro fentanyl | 2.5 | 40.00% |
| | (+)-3-cis-methyl fentanyl | 50 | 2.00% |
| | Carfentanil | 2 | 50.00% |
| | Sufentanil | 15 | 6.67% |
| | Alfentanil | 7500 | 0.01% |
| | Despropionyl fentanyl (4-ANPP) | 2,000 | 0.05% |
| | Remifentanil | 150000 | Not detected |
| | Norfentanyl | 150000 | Not detected |
| | Acetyl norfentanyl | 150000 | Not detected |
| | Norcarfentanil | 150000 | Not detected |
| | Trazodone | 25000 | 0.004% |
| NFTY5 | Fentanyl | 10 | 50% |
| | Acetyl fentanyl | 150 | 3.3% |
| | Acetyl Norfentanyl | 200 | 2.5% |
| | (±)-β-Hydroxythiofentanyl HCl | 2500 | 0.2% |
| | Acryl Fentanyl | 2500 | 0.2% |
| | Butyryl Fentanyl | 5000 | 0.1% |
| | Furanyl Fentanyl | 10000 | 0.05% |
| | Para-fluoro butyrl Fentanyl | | |
| | (P-FBF) | 80000 | 0.006% |
| | Para-fluoro Fentanyl | 40000 | 0.013% |
| | 9-HydroxyRisperidone | 10000 | 0.05% |
| | Alfentanil | 20000 | 0.025% |
| | Isobutyryl Fentanyl | 5000 | 0.1% |
| | Remifentanil | 15000 | 0.03% |
| | Valeryl Fentanyl | 20000 | 0.025% |
| | Thienyl Fentanyl | 50 | 10% |
| | (+)-3-cis-methyl fentanyl | 50 | 10% |
| | 4-Fluoro-isobutyryl Fentanyl | 30000 | Not detected |
| | Despropionyl fentanyl (4-ANPP) | 30000 | Not detected |
| | MT-45 diHCL | 150000 | Not detected |
| | Ocfentanil | 150000 | Not detected |
| | Risperidone | 150000 | Not detected |
| | Sufentanil | 150000 | Not detected |
| | Carfentanil | 150000 | Not detected |
| | Labetalol Hydrochloride | 150000 | Not detected |
| | Trazodone | 150000 | Not detected |
| | U-47700 | 150000 | Not detected |
| | ω-1-Hydroxyfentanyl | 30000 | Not detected |
| | 6-Acetyl morphine | 150000 | Not detected |

| | | | |
|---|---|---|---|
| | (±)-Amphetamine | 150000 | Not detected |
| | Buprenorphine | 150000 | Not detected |
| | Buprenorphine-3ß-D-glucuronide | 150000 | Not detected |
| | Codeine | 150000 | Not detected |
| | Dextromethorphan | 150000 | Not detected |
| | Dihydrocodeine | 150000 | Not detected |
| | EDDP | 150000 | Not detected |
| | EMDP | 150000 | Not detected |
| | Fluoxetine | 150000 | Not detected |
| | Heroin | 150000 | Not detected |
| | Hydrocodone | 150000 | Not detected |
| | Hydromorphone | 150000 | Not detected |
| | Ketamine | 150000 | Not detected |
| | Levorphanol tartrate | 150000 | Not detected |
| | Meperidine | 150000 | Not detected |
| | (±)-Methadone | 150000 | Not detected |
| | Morphine | 150000 | Not detected |
| | Morphine-3-β-D-glucuronide | 150000 | Not detected |
| | Naloxone hydrochloride | 150000 | Not detected |
| | Naltrexone hydrochloride | 150000 | Not detected |
| | Norbuprenorphine | 150000 | Not detected |
| | Norcodeine | 150000 | Not detected |
| | Norketamine | 150000 | Not detected |
| | Normeperidine | 150000 | Not detected |
| | Normorphine | 150000 | Not detected |
| | Noroxycodone | 150000 | Not detected |
| | Oxycodone | 150000 | Not detected |
| | Oxymorphone | 150000 | Not detected |
| | Pentazocine (Talwin) | 150000 | Not detected |
| | Pipamperone | 150000 | Not detected |
| | Tapentadol hydrochloride | 150000 | Not detected |
| | Thioridazine | 150000 | Not detected |
| | Tilidine | 150000 | Not detected |
| | Tramadol | 150000 | Not detected |
| | O-Desmethyl -cris-Tramadol | 150000 | Not detected |
| | N-Desmethyl -cris-Tramadol | 150000 | Not detected |
| | Norcarfentanil | 150000 | Not detected |
| THC20 | (-)-11-Nor-Δ9-THC- 9-carboxylic | 20 | 100% |
| | acid glucuronide | 30 | 66.7% |
| | (±)-11-Hydroxy-Δ9-THC | 20 | 100% |
| | (-)-11-nor-9-carboxy-Δ 9-THC | 20 | 100% |

| | | | |
|---|---|---|---|
| | (-)-Δ9-THC | 6000 | 0.3% |
| | (-)-Δ8-THC | 4000 | 0.5% |
| | Cannabinol | 8000 | 0.25% |
| | Cannabidiol | 150000 | Not detected |
| TRA100 | n-Desmethyl -cris-Tramadol | 400 | 25% |
| | o-Desmethyl -cris-Tramadol | 1000 | 10% |
| | o-Desmethyl Venlafaxine | 15000 | Not detected |
| | Venlafaxine HCl | 150000 | Not detected |

Interference:
Potential interference from compounds chemically dissimilar to the target drugs (6-Monoacetylmorphine (6-MAM10), Fentanyl (FTY1), Norfentanyl (NFTY5), Cannabinoids (THC20), and Tramadol (TRA100)) and from endogenous agents was performed by spiking the substances into pooled urine containing target drugs at near-cutoff concentrations (at +50% and -50% of cutoff). Unless otherwise indicated, substances were tested for potential interference at concentrations of 100 mg/mL. No interference was detected for following substances.

| | | |
|---|---|---|
| Acetaminophen | Effexor | Nimodipine |
| Acetophenetidin | Enalapril Maleate | Nitroglycerin |
| Acetylsalicylic Acid | Erythromycin | Norethindrone |
| Acyclovir | Esomeprazole Magnesium | N-Acetylprocainamide |
| Afrin | β-Estradiol | O-Hydroxyhippuric Acid |
| Albumin (100mg/dL) | 1% ethanol | Olanzapine |
| Aminophylline | Fenofibrate | Omeprazole |
| Aminopyrine | Fenoprofen | Oxalic Acid |
| Amiodarone Hydrochloride | Fentanyl Citrate | Oxolinic Acid |
| Amlodipine Mesylate | Fluoxetine Hydrochloride | Oxymetazoline |
| Amoxicillin | Fluvoxamine | Ondansetran |
| Ampicillin | Furosemide | Paliperidone |
| Apomorphine | Gabapentin | Pantoprazole |
| Aripiprazole | Gentisic Acid | Papaverine |
| Aspartame | Glibenclamide | Paroxetine Hydrochloride |
| Atomoxetine | Gliclazide | Penfluridol |
| Atorvastatin Calcium | Glipizide | PenicillinV Potassium |
| Atropine | Glucose | Penicillin-G |
| Benzilic Acid | Haloperidol | Phenelzine |
| Benzoic Acid | Hemoglobin | Pioglitazone Hydrochloride |
| Bilirubin | Hydrochlorothiazide | Piracetam |
| Bupropion | Hydrocortisone | Pravastatin Sodium |
| Captopril | 3-Hydroxytyramine | Prednisone |
| Carbamazepine | Isosorbide Dinitrate | Propylthiouracil |
| Cefradine | Isoxsuprine | Quetiapine Fumarate |
| Cephalexin | Ibuprofen | Quinine |
| Chloral Hydrate | Ketoconazole | Ranitidine |
| Chloramphenicol | Ketoprofen | Rifampicin |

| | | |
|---|---|---|
| Chlorothiazide | Ketamine | Risperidone |
| Cholesterol | Kratom powder | Salicylic Acid |
| Ciprofloxacin Hydrochloride | Labetalol | Serotonin |
| Citalopram | Lamotrigine | Sertraline Hydrochloride |
| Clarithromycin | Levofloxacin Hydrochloride | Sildenafil Citrate |
| Clonidine | Levonorgestrel | Simvastatin |
| Clopidogrel Hydrogen | | |
| Sulphate | Levothyroxine Sodium | Sodium Valproate |
| Clozapine | Lidocaine Hydrochloride | Spironolactone |
| Conjugated Estrogens | Lisinopril | Sulfamethazine |
| Cortisone | Lithium Carbonate | Sulindac |
| Creatinine | Liverite | Tetracycline |
| (-) Cotinine | Loperamide | Tetrahydrocortisone 3-acetate |
| chlorpheniramine | Loratadine | Tetrahydrocortisone 3- (β-D glucuronide) |
| D,L-Octopamine | Magnesium | Tetrahydrozoline |
| D,L-Propranolol | Meperidine | Thiamine |
| D,L-Tyrosine | Meprobamate | Thioridazine |
| Deoxycorticosterone | Metoprolol Tartrate | Topiramate |
| Dextromethorphan | Mifepristone | Tramadol Hydrochloride |
| Diclofenac | Mirtazapine | Trazodone Hydrochloride |
| Diflunisal | Montelukast Sodium | Triamterene |
| Digoxin | Mosapride Citrate | Trifluoperazine |
| Diphenhydramine | Minocycline | Trimethoprim |
| Dirithromycin | Nalidixic Acid | Uric Acid |
| Domperidone | Naproxen | Valproate |
| D-Pseudoephedrine | Niacinamide | Verapamil |
| Duloxetine | Nifedipine | Vitamin B2 |
| Dicyclomine | Nikethamide | Vitamin C |
| Chloroquine | Ecgonine Methyl Ester | Promethazine |

Interference by pH and specific gravity were also evaluated using pooled urine specimens containing target drugs at near-cutoff concentrations (at +50% and -50% of 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.

4. Detection Limit and Assay Reportable Range:

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

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

The stability results support a shelf life of 24 months at 2-30°C based on the real-time stability study data.

6. Assay Cut-Off:

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

## B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison results of AMP500/1000, BAR300, BUP10, BZO300, COC150/300, EDDP300, MDMA500, MET500/MET1000, MOP300, MTD300, OPI2000, OXY100, PCP25, PPX300, TCA1000 and THC50 were previously reviewed under K202567.

The method comparison study for 6-Monoacetylmorphine (6-MAM10), Fentanyl (FTY1), Cannabinoids (THC20), Tramadol (TRA100) and Norfentanyl (NFTY5), was performed in-house by three operators with 80 unaltered urine samples. These samples were blind labeled and compared to LC/MS results. The results are shown in the table below.

| Drug test | Test Cup 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%) |
|---|---|---|---|---|---|---|---|
| 6AM10 | Operator A | + | 0 | 0 | 2 | 21 | 18 |
| | | - | 13 | 14 | 11 | 1 | 0 |
| | Operator B | + | 0 | 0 | 2 | 21 | 18 |
| | | - | 13 | 14 | 11 | 1 | 0 |
| | Operator C | + | 0 | 0 | 3 | 20 | 18 |
| | | - | 13 | 14 | 10 | 2 | 0 |
| FTY1 | Operator A | + | 0 | 0 | 2 | 20 | 18 |
| | | - | 12 | 16 | 10 | 2 | 0 |
| | Operator B | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 12 | 16 | 11 | 1 | 0 |
| | Operator C | + | 0 | 0 | 3 | 20 | 18 |
| | | - | 12 | 16 | 9 | 2 | 0 |
| NFTY5 | Operator A | + | 0 | 0 | 3 | 22 | 16 |
| | | - | 10 | 16 | 11 | 2 | 0 |
| | Operator B | + | 0 | 0 | 2 | 23 | 16 |
| | | - | 10 | 16 | 12 | 1 | 0 |
| | Operator C | + | 0 | 0 | 2 | 22 | 16 |
| | | - | 10 | 16 | 12 | 2 | 0 |
| THC20 | Operator A | + | 0 | 0 | 2 | 29 | 10 |
| | | - | 9 | 15 | 14 | 1 | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Operator B | + | 0 | 0 | 2 | 29 | 10 |
| | | - | 9 | 15 | 14 | 1 | 0 |
| | Operator C | + | 0 | 0 | 2 | 29 | 10 |
| | | - | 9 | 15 | 14 | 1 | 0 |
| TRA100 | Operator A | + | 0 | 0 | 2 | 27 | 12 |
| | | - | 10 | 18 | 10 | 1 | 0 |
| | Operator B | + | 0 | 0 | 1 | 27 | 12 |
| | | - | 10 | 18 | 11 | 1 | 0 |
| | Operator C | + | 0 | 0 | 2 | 27 | 12 |
| | | - | 10 | 18 | 10 | 1 | 0 |

Discordant results:

| Drug | Operator | Sample Number | LC/MS Results (ng/mL) | Discordant Device Results |
|---|---|---|---|---|
| 6-MAM 10 | Operator A | SU25050057 | 8.193 | Positive |
| | Operator A | SU25050075 | 9.192 | Positive |
| | Operator A | SU25050041 | 10.825 | Negative |
| | Operator B | SU25050045 | 7.867 | Positive |
| | Operator B | SU25050057 | 8.193 | Positive |
| | Operator B | SU25050074 | 10.359 | Negative |
| | Operator C | SU25050043 | 7.861 | Positive |
| | Operator C | SU25050045 | 7.867 | Positive |
| | Operator C | SU25050075 | 9.192 | Positive |
| | Operator C | SU25050029 | 10.863 | Negative |
| | Operator C | SU25050015 | 10.942 | Negative |
| FTY 1 | Operator A | SU25050271 | 0.848 | Positive |
| | Operator A | SU25050284 | 0.965 | Positive |
| | Operator A | SU25050249 | 1.136 | Negative |
| | Operator A | SU25050246 | 1.218 | Negative |
| | Operator B | SU25050258 | 0.77 | Positive |
| | Operator B | SU25050249 | 1.136 | Negative |
| | Operator C | SU25050258 | 0.77 | Positive |
| | Operator C | SU25050271 | 0.848 | Positive |
| | Operator C | SU25050284 | 0.965 | Positive |
| | Operator C | SU25050270 | 1.184 | Negative |
| | Operator C | SU25050246 | 1.218 | Negative |
| NFTY 5 | Operator A | SU25060003 | 4.17 | Positive |
| | Operator A | SU25060030 | 4.765 | Positive |
| | Operator A | SU25060011 | 4.879 | Positive |
| | Operator A | SU25060065 | 5.341 | Negative |
| | Operator A | SU25060073 | 5.699 | Negative |
| | Operator B | SU25060042 | 4.315 | Positive |
| | Operator B | SU25060030 | 4.765 | Positive |
| | Operator B | SU25060075 | 5.526 | Negative |
| | Operator C | SU25060042 | 4.315 | Positive |

| | | | | |
|---|---|---|---|---|
| | Operator C | SU25060011 | 4.879 | Positive |
| | Operator C | SU25060075 | 5.526 | Negative |
| | Operator C | SU25060073 | 5.699 | Negative |
| THC 20 | Operator A | SU25050194 | 18.614 | Positive |
| | Operator A | SU25050181 | 19.363 | Positive |
| | Operator A | SU25050220 | 20.645 | Negative |
| | Operator B | SU25050185 | 18.422 | Positive |
| | Operator B | SU25050194 | 18.614 | Positive |
| | Operator B | SU25050167 | 20.499 | Negative |
| | Operator C | SU25050185 | 18.422 | Positive |
| | Operator C | SU25050181 | 19.363 | Positive |
| | Operator C | SU25050167 | 20.499 | Negative |
| TRA 100 | Operator A | SU25050130 | 98.136 | Positive |
| | Operator A | SU25050098 | 98.772 | Positive |
| | Operator A | SU25050144 | 108.094 | Negative |
| | Operator B | SU25050130 | 98.136 | Positive |
| | Operator B | SU25050120 | 102.471 | Negative |
| | Operator C | SU25050135 | 83.391 | Positive |
| | Operator C | SU25050098 | 98.772 | Positive |
| | Operator C | SU25050120 | 102.471 | Negative |

2. Matrix Comparison:

   Not applicable.

## C Clinical Studies:

1. Clinical Sensitivity:

2. Clinical Specificity:

3. Clinical Cut-Off:

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   A lay user study was performed involving a total of 140 participants from 3 sites. 68 males and 72 females tested one configuration of SAFElifeTM T-Dip Multi-Drug Urine Test Panel, including 6-MAM10, THC20, TRA100, NFTY5, AMP1000, BAR300, BUP10, BZO300, COC300, FTY1, mAMP1000, MDMA500, MTD300, OPI2000, OXY100. Each participant was provided one package insert, one blind labeled test solution, and one test device. Test solutions were randomly assigned to participants, one for each. Following testing, users completed a study questionnaire to assess usability and user comprehension, and the results from this questionnaire were found to be acceptable. Participants aged 18 and over, with diverse educational backgrounds, were recruited. Results from the lay user testing are provided in the table below. Lay user results of AMP500, COC150, EDDP300, MET500,

MOP300, PCP25, PPX300, TCA1000, and THC50 were previously reviewed under K202567.

| Drug | Cutoff (ng/mL) | Results | Concentration | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | -100% cutoff | -75% cutoff | -50% cutoff | -25% cutoff | +25% cutoff | +50% cutoff | +75% cutoff |
| 6-MAM | 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% |
| AMP | 1000 | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| BAR | 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% |
| 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% |
| 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% |
| COC | 150 | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| FTY | 1 | 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% |
| mAMP | 1000 | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 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% |
| MTD | 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% |
| NFTY | 5 | 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% |
| OPI | 2000 | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| OXY | 100 | 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 | 20 | 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% |
| TRA | 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% |

**D Expected Values/Reference Range:**

Not applicable.

## VIII Proposed Labeling:

The labeling support 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.