April 28, 2026

Guangzhou Wondfo Biotech Co., Ltd.
Kaiyu Xiao
Senior Regulatory Affairs Manager
#8 Lizhishan Rd., Science City, Huangpu District
Guangzhou, 510663
China

Re: K260065
Trade/Device Name: SAFElife™ T-Dip Multi-Drug Urine Test Panel; SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT NGL PTH NFV NFY PTG NGG LCM QBF QAW NFW
Dated: March 24, 2026
Received: March 24, 2026

Dear Kaiyu Xiao:

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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.04.28 07:46:40 -04'00'

Joseph Kotarek
Branch Chief for Toxicology
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. K260065 ?

Please provide the device trade name(s). ?

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

Please provide your Indications for Use below. ?

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 listed above 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 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:

Drug (Identifier)	Calibrator	Cut-off Level
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-diphenyl-pyrrolidine	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 listed above 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.

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) SUMMARY

K260065

1. **Date:** April 28, 2026

2. **Submitter:** Guangzhou Wondfo Biotech Co., Ltd.

   No.8 Lizhishan Road, Science City, Huangpu District

   Guangzhou, China

3. **Contact Person** Kaiyu Xiao

   Senior Regulatory Affairs Manager

   Tel: +86-15005196892

   E-mail: kaiyu.xiao@wondfo.com.cn

4. **Device Name** SAFElife™ T-Dip Multi-Drug Urine Test Panel

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

5. **Classification** Class II

Product Code &Target Drug	Regulation Section	Panel
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology (91)
NGL Buprenorphine (BUP) Morphine (MOP) Opiates (OPI) Oxycodone (OXY) Fentanyl (FTY) Norfentanyl (NFTY) Tramadol (TRA) 6-Monoacetylmorphine(6-MAM)	862.3650, Opiate Test System	Toxicology (91)
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology (91)
NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology (91)
NFY Cocaine (COC)	862.3250, Cocaine Test System	Toxicology (91)
PTG 2-ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) Methadone (MTD)	862.3620, Methadone Test System	Toxicology (91)
NGG Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology (91)

Methylenedioxymethamphetamine (MDMA)		
LCM Phencyclidine (PCP)	Unclassified	Toxicology (91)
QBF Propoxyphene (PPX)	862.3700, Propoxyphene test system.	Toxicology (91)
QAW Nortriptyline (TCA)	862.3910, Tricyclic antidepressant drugs test system	Toxicology (91)
NFW Cannabinoids (THC)	862.3870, Cannabinoids Test System	Toxicology (91)

6. Predicate Device

Product name: Wondfo T-Dip Multi-Drug Urine Test Panel, Wondfo T-Dip Multi-Drug Urine Test Panel Rx

510(k) Number: K202567

7. Intended Use

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 listed above 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 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:

Drug (Identifier)	**Calibrator**	**Cut-off Level**
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-diphenyl-pyrrolidine	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 listed above 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.

8. 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. SAFElife™ Multi-Drug Urine Test Panel and SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx have a general identical design.

9. Comparison with Predicate

A summary comparison of features of the candidate device with the predicate device is provided in following table.

Table 1: Features Comparison of SAFElife™ T-Dip Multi-Drug Urine Test Panel and the predicate device

Item	**Candidate Device**		**Predicate - K202567**
Device Trade Name	SAFElife™ T-Dip Multi-Drug Urine Test Panel SAFElife™ T-Dip Multi-Drug Urine Test Panel Dx		Wondfo T-Dip Multi-Drug Urine Test Panel, Wondfo T-Dip Multi-Drug Urine Test Panel Rx
General Device Similarities			
Indications For Use	Drugs of abuse testing in human urine		Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction		Same
Type of Test	Qualitative		Same
Specimen Type	Human urine		Same
General Device Characteristic Differences			
Analytes and Cutoff	Target Drugs	Cutoff	Same
	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	

Item	Candidate Device		Predicate - K202567
	Nortriptyline (TCA)	1000 ng/mL	
	Cannabinoids (THC)	50 ng/mL	
	6-Monoacetylmorphine (6-MAM)	10 ng/mL	Not included in K202567
	Fentanyl (FTY)	1 ng/mL	
	Norfentanyl (NFTY)	5 ng/mL	
	Cannabinoids (THC)	20 ng/mL	
	Tramadol (TRA)	100 ng/mL	

10. Test Principle

SAFElife™ T-Dip Multi-Drug Urine Test Panel is a lateral flow chromatographic immunoassay. When urine sample is added to the panel device, urine is absorbed into the test strip and migrates upwards by capillary action. If the concentration of target drug presented in the urine sample is below the cutoff level, the target drug will not saturate the binding sites of its specific monoclonal antibody-coated particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored band will be formed on the test line region. If the concentration of target is beyond the cutoff level, the target drug will saturate the binding sites of its specific monoclonal antibody-particles, thus the antibody-coated particles will not be captured by immobilized drug-conjugate hence no colored band will be formed on the test line region. A band should be formed on the control line region regardless of the presence of target drug or metabolite in the sample to indicate that the tests have been performed properly.

11. Performance Characteristics

1. Analytical Performance

Performance data of AMP500/1000, BAR300, BUP10, BZO300, COC150/300, EDDP300, MDMA500, MET500/MET1000, MOP300, MTD300, OPI2000, OXY100, PCP25, PPX300, TCA1000 and THC50 were presented in the 510(k)-cleared submission K202567. In this submission, 6-Monoacetylmorphine (6-MAM10), Fentanyl (FTY1), Norfentanyl (NFTY5), Cannabinoids (THC20), and Tramadol (TRA100) study data are summarized and presented below.

a 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. 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:

Drug	Lot Number	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
6-MAM 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+
NFTY5	Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	1-/49+	0-/50+	0-/50+	0-/50+
	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+
TRA100	Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	0-/50+	0-/50+	0-/50+	0-/50+
	Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	0-/50+	0-/50+	0-/50+	0-/50+
	Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	0-/50+	0-/50+	0-/50+	0-/50+

b Linearity/assay reportable range

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

c Stability

The devices are stable at 2-30℃ for 24 months based on the real-time stability study data.

d Analytical specificity

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; compounds that did not yield a positive result at the highest concentration tested have relative cross reactivity results represented by a dash in the table below.

Drug/Cutoff	**Compound**	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
6-MAM10	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

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	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%

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	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

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	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

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	O-Desmethyl -cris-Tramadol	150000	Not detected
	N-Desmethyl -cris-Tramadol	150000	Not detected
	Norcarfentanil	150000	Not detected
THC 20	(−)-11-nor-9-carboxy-Delta8-THC	20	100%
	(-)-11-Nor-Δ9-THC- 9-carboxylic 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

e 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 μg/mL.

The following substances demonstrated no positive. The following substances demonstrated no positive or negative interference on the assays encompassed in this submission.

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

ƒ *Urine Density&pH*

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.

2. Method comparison Studies

Comparison Study Performance data of AMP500/1000, BAR300, BUP10, BZO300, COC150/300, EDDP300, MDMA500, MET500/MET1000, MOP300, MTD300, OPI2000, OXY100, PCP25, PPX300, TCA1000 and THC50 were presented in the cleared 510(k) K202567 submission.

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

Drug	Operator	Results	Drug-free by LC/MS	Low Neg by LC/MS (less than -50%)	Near Cutoff Neg by LC/MS (Between -50% and the Cutoff)	Near Cutoff Pos by LC/MS (Between the cutoff and +50%)	High Pos by LC/MS (greater than +50%)
6-MAM 10	A	Positive	0	0	2	21	18
		Negative	13	14	11	1	0
	B	Positive	0	0	2	21	18
		Negative	13	14	11	1	0
	C	Positive	0	0	3	20	18
		Negative	13	14	10	2	0
FTY 1	A	Positive	0	0	2	20	18
		Negative	12	16	10	2	0
	B	Positive	0	0	1	21	18
		Negative	12	16	11	1	0
	C	Positive	0	0	3	20	18
		Negative	12	16	9	2	0
NFTY 5	A	Positive	0	0	3	22	16
		Negative	10	16	11	2	0
	B	Positive	0	0	2	23	16
		Negative	10	16	12	1	0
	C	Positive	0	0	2	22	16
		Negative	10	16	12	2	0
THC 20	A	Positive	0	0	2	29	10
		Negative	9	15	14	1	0

Drug	Operator	Results	Drug-free by LC/MS	Low Neg by LC/MS (less than -50%)	Near Cutoff Neg by LC/MS (Between -50% and the Cutoff)	Near Cutoff Pos by LC/MS (Between the cutoff and +50%)	High Pos by LC/MS (greater than +50%)
	B	Positive	0	0	2	29	10
		Negative	9	15	14	1	0
	C	Positive	0	0	2	29	10
		Negative	9	15	14	1	0
TRA 100	A	Positive	0	0	2	27	12
		Negative	10	18	10	1	0
	B	Positive	0	0	1	27	12
		Negative	10	18	11	1	0
	C	Positive	0	0	2	27	12
		Negative	10	18	10	1	0

Discordant Results are summarized below:

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

Drug	Operator	Sample Number	LC/MS Results (ng/mL)	Discordant Device Results
	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

3. Lay-user study

A lay user study was presented in the cleared 510(k) K202567 submission involving a total of 280 participants from 3 sites. 94 males and 46 females tested T-Dip® Multi-Drug Urine Test Panel Configuration 1 (including AMP 500, BAR 300, BUP 10, BZO 300, COC 150, EDDP 300, MDMA 500, MET 500, MOP 300, MTD 300, OXY 100, PCP 25, PPX 300, TCA 1000, THC 50); 88 male and 52 females tested T-Dip® Multi-Drug Urine Test Panel Configuration 2 (Group 2, including AMP 1000, BAR 300, BUP 10, COC 300, EDDP 300, MDMA 500, MET 1000, OPI 2000, MTDD 300, OXY 100, PCP 25, PPX 300, TCA 1000, THC 50).

In this submission, A lay user study was performed involving a total of 140 participants from 3 sites. 68 males and 72 females tested one configuration of SAFElife™ 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 below table:

Drug/ Cutoff	Result	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
6-MAM10	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%
AMP1000	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%
BAR300	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%
BUP10	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%
BZO300	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%
COC300	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%
FTY1	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%
MDMA500	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20

Drug/ Cutoff	Result	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
	Total	20	20	20	20	20	20	20
	Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MTD300	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%
NFTY5	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%
OPI2000	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%
OXY100	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%
THC20	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%
TRA100	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%

Lay users completed given surveys on the ease of understanding the package insert. 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.

4. Clinical Study

Not applicable.

12. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison and Lay-user studies of the devices, it's concluded a substantial equivalence decision.