510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K230238

B Applicant

Shenzhen Bioeasy Biotechnology Co., Ltd.

C Proprietary and Established Names

BIOEASY™ U-Catch MAX Multi-Drug Test Cup, BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NFT	Class II	21 CFR 862.3100 - Amphetamine Test System	TX - Clinical Toxicology
NFW	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
NFY	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
NGG	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
NGL	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology
NFV	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology

PTG	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
PTH	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
NGM	Unclassified		
QAW	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology
QBF	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology
DJG	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

Modification of a previously cleared device (K182530) to add Amphetamine (500 ng/mL cutoff), Methamphetamine (500 ng/mL cutoff), Cocaine (150 ng/mL cutoff), EDDP (300 ng/mL cutoff), and 6-Acetylmorphine (10 ng/mL cutoff).

B Measurand:

Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline, Cannabinoids and 6-Acetylmorphine

C Type of Test:

Qualitative lateral flow immunochromatographic assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

BIOEASY™ U-Catch MAX Multi-Drug Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine,

Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

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

BIOEASY™ U-Catch MAX Multi-Drug 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, Oxazepam, Secobarbital, d-Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be 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.

BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline, Cannabinoids and 6-Acetylmorphine in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL

Cocaine (COC)	150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300)	300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
d-Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC)	50 ng/mL
6-Acetylmorphine	10 ng/mL

BIOEASY™ U-Catch MAX Multi-Drug 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, Oxazepam, Secobarbital, d-Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be 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 BIOEASY™ U-Catch MAX Multi-Drug Test Cup and the BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx are immunochromatographic assays that use a lateral flow system for the qualitative detection of target drugs and drug metabolites in human urine. The products are single-use in vitro diagnostic devices. The candidate device contains a Cup device, a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

The BIOEASY™ U-Catch MAX Multi-Drug Test Cup (OTC use) detects all analytes listed above except 6-Acetylmorphine.

The BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx (Prescription Use) detects all analytes listed above.

B Principle of Operation:

The candidate devices are rapid tests for the qualitative detection of target drugs and 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):

AssureTech DOA Dipstick Screen Panel Tests, AssureTech DOA Integrated Cup Tests

B Predicate 510(k) Number(s):

K201630

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230238	K201630
Device Trade Name	BIOEASY™ U-Catch MAX Multi-Drug Test Cup, BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx	AssureTech DOA Dipstick Screen Panel Tests, AssureTech DOA Integrated Cup Tests
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative determination of drugs-of-abuse in human urine.	Same
Specimen	Human urine	Same
Methodology	Competitive binding, Lateral flow Immuno-chromatographic assay based on the principle of antigen antibody	Same

	immunochemistry	
Cutoff	Amphetamine (AMP): 500 ng/ml Oxazepam (BZO): 300 ng/ml Cocaine (COC): 150 ng/ml Methamphetamine (MET): 500 ng/ml Morphine (MOR): 300 ng/mL Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxymethamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 300 ng/ml d-Propoxyphene (PPX): 300 ng/ml	Same
General Device Characteristic Differences		
Intended users	Over the Counter (OTC) Use and Prescription Use	Prescription Use Only
Marijuana (11-Nor-△9-Tetrahydrocannabinol-9-COOH) (THC)	50 ng/ml	20 ng/mL

VI Standards/Guidance Documents Referenced:

None referenced.

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. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were tested in a blinded fashion. For each concentration, tests were performed in two runs per day for 25 days per device in a randomized order using 3 reagent lots. The results obtained are summarized in the following tables for Amphetamine 500, Cocaine 150, Methamphetamine 500, 2- ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), and 6-acetylmorphine (6-AM). The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Oxazepam, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Cannabinoids were previously reported in K182530.

Drug test	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
AMP 500	Negative	50	0	50	0	50	0	0
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	cutoff	50	28	22	24	26	24	26
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
COC 150	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	cutoff	50	22	28	21	29	28	22
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
MET 500	Negative	50	0	50	0	50	0	50
	-75%cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	cutoff	50	23	27	27	23	25	25
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
EDDP 300	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	cutoff	50	26	24	24	26	25	25
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0
6-AM 10	Negative	50	0	50	0	50	0	50
	-75% cutoff	50	0	50	0	50	0	50
	-50% cutoff	50	0	50	0	50	0	50
	-25% cutoff	50	0	50	0	50	0	50
	cutoff	50	24	26	26	24	27	23

Drug test	% of cutoff	Number of Determinations per lot	Result					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
	+25% cutoff	50	50	0	50	0	50	0
	+50% cutoff	50	50	0	50	0	50	0
	+75% cutoff	50	50	0	50	0	50	0
	+100% cutoff	50	50	0	50	0	50	0

2. Linearity:

Not Applicable.

3. Analytical Specificity/Interference:

Cross-Reactivity:
To test cross-reactivity, 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 concentration that caused a positive result for each compound is listed below for Amphetamine 500, Cocaine 150, Methamphetamine 500, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), and 6-acetylmorphine (6-AM). The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Oxazepam, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Cannabinoids were reported in K182530.

AMP500 (Cutoff=500 ng/mL)	**Result Positive at (ng/ml)**	**%Cross-Reactivity**
D - Amphetamine	500	100%
L - Amphetamine	10000	5%
DL - Amphetamine	1500	33%
Phentermine	15000	3.3%
Hydroxyamphetamine	4000	12.5%
Methylenedioxyamphetamine (MDA)	10000	5%
d-Methamphetamine	＞100000	＜0.5%
1-Methamphetamine	＞100000	＜0.5%
Ephedrine	＞100000	＜0.5%
Methylenedioxyethylamphetamine	＞100000	＜0.5%
3,4-methylenedioxymethamphetamine (MDMA)	＞100000	＜0.5%

COC150 (Cutoff=150 ng/mL)	**Result Positive at (ng/ml)**	**%Cross-Reactivity**
Benzoylecgonine	150	100%
Cocaine HCl	375	40%
Cocaethylene	6250	2.4%

Ecgonine	16000	0.9%
Norcocaine	50000	0.3%

MET500 (Cutoff=500 ng/mL)	**Result Positive at (ng/ml)**	**%Cross-Reactivity**
D(+)-Methamphetamine	500	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	5000	10%
D/L-Methamphetamine	500	100%
p-Hydroxymethamphetamine	5000	10%
D-Amphetamine	＞ 100000	＜0.5%
L-Amphetamine	＞100000	＜0.5%
Chloroquine	25000	2%
(+/-)-Ephedrine	2000	25%
L-Methamphetamine	5000	10%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	＞ 100000	＜0.5%
β-Phenylethylamine	3750	13.3%
Trimethobenzamide	10000	5%
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	5000	10%

EDDP (Cutoff=300 ng/mL)	**Result Positive at (ng/ml)**	**% Cross-Reactivity**
EDDP	300	100%
Methadone	300000	0.1%
Doxylamine	＞100000	＜0.3%
LAAM HCl	＞100000	＜0.3%
Alpha Methadol	＞100000	＜0.3%
Disopyramide	＞100000	＜0.3%
EMDP	＞100000	＜0.3%

6-AM (Cutoff=10 ng/mL)	**Result Positive at (ng/ml)**	**% Cross-Reactivity**
6-acetylmorphine	10	100%
Acetylcodeine	>10000	<0.1%
Buprenorphine	>10000	<0.1%
Codeine	>10000	<0.1%
Diacetylmorphine	1000	0.01%
Dihydrocodeine	>10000	<0.1%
Ethylmorphine	>10000	<0.1%
Hydrocodone	>10000	<0.1%

Hydromorphone	5000	0.002%
Morphine	10000	0.001%
Morphine-3-glucuronide	>10000	<0.1%
Nalorphine	5000	0.002%
Thebaine	>20000	<0.05%
Dextromethorphan	>100,000	<0.01%
Heroin	100000	0.0001%
Imipramine	>100,000	<0.01%
LAAM (Levacetylmethadol)	>100,000	<0.01%
Levorphanol	>100,000	<0.01%
Meperidine	>100,000	<0.01%
Methadone	>100,000	<0.01%
Mitragynine (kratom)	>20,000	<0.05%
Morphine 6-D-glucuronide	>100,000	<0.01%
Naloxone	>100,000	<0.01%
Naltrexone	>100,000	<0.01%
Naproxen	>100,000	<0.01%
Norbuprenorphine	>10,000	<0.1%
Norbuprenorphine glucuronide	>100,000	<0.01%
Norcodeine	>100,000	<0.01%
Norhydrocodone	>100,000	<0.01%
Normorphine	>100,000	<0.01%
Noroxycodone	>100,000	<0.01%
Noroxymorphone	>100,000	<0.01%
Norpropoxyphene	>100,000	<0.01%
Oxycodone	>100,000	<0.01%
Oxymorphone	>100,000	<0.01%
Oxymorphone-3β-D-glucuronide	>100,000	<0.01%
Tapentadol HCl	>100,000	<0.01%
Tramadol	>100,000	<0.01%

Interfering substances:
Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and urine samples with concentrations of the target drugs at 25% below and 25% above cutoff levels. These urine samples were tested using three lots of each device. The compounds were tested at 100 ug/mL (unless otherwise noted in the table). No interference was observed for any of the compounds tested, and the list of compounds is provided in the following table.

Acetaminophen	Creatinine	Ketamine	Prednisone
Acetophenetidin	Deoxycorticosterone	Ketoprofen	(±)-Propranolol

N-Acetylprocainamide	Dextromethorphan	Labetalol	Pseudoephedrine
Acetylsalicylic acid	Diclofenac	Loperamide	Quinine
Albumin (100mg/dL)	Diflunisal	Meperidine	Ranitidine
Aminopyrine	Digoxin	Meprobamate	Salicylic acid
Amoxicillin	Diphenhydramine	Methoxyphenamine	Serotonin (5-Hydroxytyramine)
Ampicillin	1% Ethanol	Nalidixic acid	Sulfamethazine
Apomorphine	Ecgonine methyl ester	Naloxone	Sulindac
Ascorbic acid	β-Estradiol	Naltrexone	Tetrahydrocortisone 3-(β- Dglucuronide)
Aspartame	Erythromycin	Naproxen	Tetrahydrocortisone 3-acetate
Atropine	Fenoprofen	Niacinamide	Tetrahydrozoline
Benzilic acid	Furosemide	Nifedipine	Thiamine
Benzoic acid	Gentisic acid	Norethindrone	Thioridazine
Bilirubin (500 µg/mL)	Hemoglobin	Noscapine	Triamterene
Chloral hydrate	Hydralazine	(±)-Octopamine	Trifluoperazine
Chloramphenicol	Hydrochlorothiazide	Oxalic acid	Trimethoprim
Chlorothiazide	Hydrocortisone	Oxolinic acid	DL-Tryptophan
Chlorpromazine	O-Hydroxyhippuric acid	Oxymetazoline	Tyramine
Cholesterol	3-Hydroxytyramine	Papaverine	DL-Tyrosine
Clonidine	Ibuprofen	Penicillin G	Uric acid
Cortisone	Isoproterenol	Perphenazine	Verapamil
(-)-Cotinine	Isoxsuprine	Phenelzine	Zomepirac

Effect of Urinary Specific Gravity and pH:
To investigate the effect of urine specific gravity and urine pH, urine samples, with specific gravity ranging from 1.000 to 1.035 or urine samples with pH ranging from 4 to 9 were spiked with the target drugs to concentrations at 25% below and 25% above cutoff levels. These samples were tested using three lots of each device. Results were all positive for samples at +25% cutoff and all negative for samples at -25% cutoff.

4. Assay Reportable Range:

   Not applicable.

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

   The device is traceable to commercially available reference materials.

6. Detection Limit:

   Not applicable.

7. Assay Cutoff:

Refer to Section VII.A.1

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies for the BIOEASY U-Catch MAX Multi-Drug Test Cup Rx were performed by three operators. Eighty (80) unaltered clinical samples were run for each target drug. The samples were tested in a blinded fashion and compared to LC/MS results. The results are presented in the tables below for Amphetamine 500, Cocaine 150, Methamphetamine 500, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), and 6-acetylmorphine (6-AM). The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Oxazepam, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Cannabinoids were previously reported in K182530.

AMP 500:

BIOEASY U-Catch MAX Multi- Drug Test Cup Rx		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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	3	17	20
	Negative	7	16	14	3	0
Viewer B	Positive	0	0	2	18	20
	Negative	7	16	15	2	0
Viewer C	Positive	0	0	3	18	20
	Negative	7	16	14	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	AMPLC063	473	Positive
Viewer C	AMPLC063	473	Positive
Viewer B	AMPLC040	477	Positive
Viewer A	AMPLC039	490	Positive
Viewer B	AMPLC039	490	Positive
Viewer C	AMPLC039	490	Positive
Viewer A	AMPLC004	494	Positive
Viewer C	AMPLC004	494	Positive
Viewer A	AMPLC018	520	Negative
Viewer B	AMPLC018	520	Negative
Viewer A	AMPLC064	525	Negative

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	AMPLC064	525	Negative
Viewer C	AMPLC064	525	Negative
Viewer A	AMPLC009	540	Negative
Viewer C	AMPLC014	570	Negative

COC 150

BIOEASY U-Catch MAX Multi- Drug Test Cup Rx		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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	19
	Negative	7	16	15	2	0
Viewer B	Positive	0	0	2	18	19
	Negative	7	16	15	3	0
Viewer C	Positive	0	0	2	19	19
	Negative	7	16	15	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	COCLC046	139	Positive
Viewer A	COCLC019	142	Positive
Viewer C	COCLC019	142	Positive
Viewer B	COCLC026	142	Positive
Viewer A	COCLC060	145	Positive
Viewer C	COCLC060	145	Positive
Viewer A	COCLC049	154	Negative
Viewer B	COCLC049	154	Negative
Viewer C	COCLC049	154	Negative
Viewer A	COCLC024	157	Negative
Viewer B	COCLC062	157	Negative
Viewer C	COCLC062	157	Negative
Viewer B	COCLC029	159	Negative

MET 500

BIOEASY U-Catch MAX Multi- Drug Test Cup Rx		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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	17	20
	Negative	7	16	15	3	0
Viewer B	Positive	0	0	3	18	20
	Negative	7	16	14	2	0
Viewer C	Positive	0	0	2	17	20
	Negative	7	16	15	3	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	METL055	427	Positive
Viewer B	METL005	447	Positive
Viewer C	METL005	447	Positive
Viewer A	METL020	465	Positive
Viewer B	METL020	465	Positive
Viewer A	METL063	486	Positive
Viewer C	METL063	486	Positive
Viewer B	METL053	525	Negative
Viewer C	METL053	525	Negative
Viewer A	METL060	530	Negative
Viewer C	METL060	530	Negative
Viewer A	METL036	540	Negative
Viewer B	METL036	540	Negative
Viewer A	METL059	555	Negative
Viewer C	METL059	555	Negative

EDDP

BIOEASY U-Catch MAX Multi- Drug Test Cup Rx		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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	18	20
	Negative	6	18	14	2	0
Viewer B	Positive	0	0	2	18	20
	Negative	6	18	14	2	0

BIOEASY U-Catch MAX Multi- Drug Test Cup Rx		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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer C	Positive	0	0	3	18	20
	Negative	6	18	13	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	EDDPLC042	244	Positive
Viewer C	EDDPLC042	244	Positive
Viewer B	EDDPLC004	291	Positive
Viewer C	EDDPLC004	291	Positive
Viewer A	EDDPLC051	294	Positive
Viewer B	EDDPLC051	294	Positive
Viewer C	EDDPLC051	294	Positive
Viewer A	EDDPLC074	303	Negative
Viewer B	EDDPLC074	303	Negative
Viewer C	EDDPLC074	303	Negative
Viewer B	EDDPLC052	327	Negative
Viewer A	EDDPLC018	330	Negative
Viewer C	EDDPLC018	330	Negative

6-AM

BIOEASY U-Catch MAX Multi- Drug Test Cup Rx		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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	16	22
	Negative	6	17	15	2	0
Viewer B	Positive	0	0	2	16	22
	Negative	6	17	15	2	0
Viewer C	Positive	0	0	2	15	22
	Negative	6	17	15	3	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	6-AMLC016	9.23	Positive

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	6-AMLC074	9.68	Positive
Viewer C	6-AMLC074	9.68	Positive
Viewer B	6-AMLC026	9.93	Positive
Viewer A	6-AMLC037	9.95	Positive
Viewer C	6-AMLC037	9.95	Positive
Viewer A	6-AMLC009	10.3	Negative
Viewer C	6-AMLC009	10.3	Negative
Viewer B	6-AMLC027	11.1	Negative
Viewer C	6-AMLC027	11.1	Negative
Viewer A	6-AMLC038	11.4	Negative
Viewer B	6-AMLC038	11.4	Negative
Viewer C	6-AMLC035	11.8	Negative

Lay user study

A lay user study was performed using the BIOEASY U-Catch MAX Multi-Drug Test Cup at three intended use sites with 140 lay persons. The lay users had diverse ages and educational and professional backgrounds. Urine samples were prepared at multiple concentrations (Negative (-100%), +/-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 tested in a blinded fashion. Each participant was provided with the package insert, one blind-labeled sample and a device, and no additional training. Summary results are shown below:

Drugs	**% of Cutoff**	**Number of samples**	**Lay person results**		**The percentage of correct results (%)**
			No. of Positive	**No. of Negative**	
AMP	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	0	20	100
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
BAR	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	0	20	100
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
	+75% cutoff	20	20	0	100
COC	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
BZO	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
MET	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	0	20	100
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
MTD	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	0	20	100
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
MOP	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	0	20	100

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
OXY	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
THC	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
TCA	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	0	20	100
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
BUP	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
PCP	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
MDMA	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	0	20	100
	+25% cutoff	20	19	1	95
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
EDDP	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	20	0	100
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100
PPX	-100% cutoff	20	0	20	100
	-75% cutoff	20	0	20	100
	-50% cutoff	20	0	20	100
	-25% cutoff	20	1	19	95
	+25% cutoff	20	20	0	100
	+50% cutoff	20	20	0	100
	+75% cutoff	20	20	0	100

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):

Read Time:
The sponsor provided data to support the recommendation for read time. The sponsor recommends that the results should be read 5-30 minutes after testing.

D Clinical Cutoff:

Not Applicable.

E 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.