February 6, 2023

Xenta Biomedical Science Co., Ltd.
Huang Ling
Product Manager
Building C5, 9th Floor, Rm 901, No. 11 Kaiyuan Avenue
Huangpu District
Guangzhou, Guangdong 510535
China

Re: K222955
Trade/Device Name: Xenta Drug Screen Cup, Xenta Drug Screen Dipcard
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, DIO, LDJ, DJC
Dated: September 27, 2022
Received: September 27, 2022

Dear Huang Ling:

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 (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 located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Paula Caposino -S

Digitally signed by Paula Caposino -S
Date: 2023.02.06 13:24:53 -05'00'

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
k222955

Device Name
Xenta Drug Screen Cup
Xenta Drug Screen Dipcard

Indications for Use *(Describe)*
Xenta Drug Screen Cup and Xenta Drug Screen Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off level
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL
Morphine 300 (MOP)	Morphine	300 ng/mL

The tests contain two formats: 1) Test Cup and 2) Test Dipcard. The tests may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above. These tests are intended for in vitro diagnostics use. They are intended for prescription use.

The assays provide only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Section 5 - 510(k) Summary

Date of Summary Preparation: 2/2/2023
510(k) Number: K222955

1. Submitter's Identifications

Submitter: Xenta Biomedical Science Co., Ltd.
Address: Building C5, 9th Floor, Rm 901, No. 11 Kaiyuan Avenue, Huangpu District, Guangzhou, 510535, P.R. China
Contact Person: Huang Ling
Contact Email Address: 1433969171@qq.com
Telephone: +86-20-31707187
Fax: +86-20-31707187

2. Correspondent's Identifications

Correspondent's Name: Xenta Biomedical Science Co., Ltd.
Address: Building C5, 9th Floor, Rm 901, No. 11 Kaiyuan Avenue, Huangpu District, Guangzhou, 510535, P.R. China
Contact Person: Huang Ling
Contact Email Address: 1433969171@qq.com
Telephone: 86-20-31707187
Fax: 86-20-31707187

3. Name of the Device

Proprietary names:

Xenta Drug Screen Cup
Xenta Drug Screen Dipcard

Recommended classification regulation:

21 CFR 862.3250 Cocaine test system
21 CFR 862.3650 Morphine test system
21 CFR 862.3870 Cannabinoid test system
21 CFR 862.3610 Methamphetamine test system

Device class: Class Ⅱ
Panel: Toxicology
Product code: DIO,DJG,LDJ,DJC

4. The Predicate Devices

K153050 Rapid Single/Multi-drug Test Cup
Rapid Single/Multi-drug Test Dipcard

5. Device Description

Xenta Drug Screen Cup and Xenta Drug Screen Dipcard are competitive binding, lateral flow immunochromatographic assays for the qualitative detection of Cocaine, Marijuana, Methamphetamine, Morphine, Methylenedioxymethamphetamine at or above the cut-off levels as indicated. The tests are performed without the use of an instrument.
The test cup and test dipcard formats use identical test strips made with the same chemical formulation and manufacturing procedures.

6. Indications for Use

Xenta Drug Screen Cup and Xenta Drug Screen Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off level
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Methylenedioxymethampheta mine (MDMA)	3,4-Methylenedioxymetham phetamine	500 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL
Morphine 300 (MOP)	Morphine	300 ng/mL

The tests contain two formats:1) Test Cup and 2) Test Dipcard. The tests may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above. These tests are intended for in vitro diagnostics use. They are intended for prescription use.
The assays provide only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

7. Comparison to Predicate Devices:

A summary comparison of features of the Xenta Drug Screen Cup and Xenta Drug Screen Dipcard and the predicate devices is provided in the following Table：

Item	Device	Predicate （K153050）
Indication for use	Qualitative detection of drugs-of-abuse in urine （Cocaine ,Morphine, Methamphetamine, Marijuana, Methylenedioxymethamphetamine)	Same （but the number of drugs detected different)
Intended Users	Prescription Use	Over the Counter (OTC) Use and

		Prescription Use
Specimen	Urine	Same
Cutoff	Cocaine:300 ng/mL Methamphetamine:1000 ng/mL Morphine:300 ng/mL Marijuana:50 ng/mL Methylenedioxymethamphetamine:500 ng/mL	Cocaine:300 ng/mL Methamphetamine:1000 ng/mL Morphine:300 ng/mL Marijuana:50 ng/mL Methylenedioxymethamphetamine: 500 ng/mL
Read time	5 minutes	Same
Results	Qualitative	Same
Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Dipcard and Cup	Cassette,Dip Card and Cup

8. Performance Data:

8.1 Cross-reactivity with structurally similar compounds

To test the cross reactivity of the test, 2 lots of test Dipcard and one lot of test Cup was used to test with drug metabolites and drug structurally similar compounds in urine. All the components were added to drug-free normal human urine. Each sample was tested in 5 replicates using 3 lots of Test Cup and Test Dipcard. If any positive result was observed, the compounds were further diluted with known drug-free urine specimen sequentially to different concentrations and tested in quintuplicate, until the highest concentration that generates a negative result was identified.
The cross reacting substances with the lowest concentration that produced a positive result was identified and is listed in the table below. If no cross reactivity was observed the highest concentration tested is shown.

Cannabinoids (THC)	Lowest Concentration (ng/mL)	% Cross-reactivity	**Methylenedioxymethamphetamine (MDMA)**	Lowest Concentration (ng/mL)	% Cross-reactivity
11-nor-Δ9-THC-9-COOH	50	100%	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
11-nor-Δ8-THC-9-COOH	50	100%	3,4-methylenedioxyamphetamine (MDA)	2200	22.7%
Δ 9-THC	15000	0.3%	3,4-Methylenedioxyethylamphetamine (MDEA)	240	208.3%
Δ 8-THC	10000	0.5%	D-methamphetamine(MAMP)	100000	0.5%
Cannabidiol	20000	0.3%	D-Amphetamine	>100000	<0.5%
Cannabinol	＞100000	<0.05%	L-Amphetamine	>100000	<0.5%
(+/-)11-hydroxy-Δ9-THC	5000	1%	L-Methamphetamine	>100000	<0.5%
Methamphetamine (MET)			**Morphine 300（MOP）**		

d-Methamphetamine	1000	100%	Morphine	300	100.0%
l-Methamphetamine	8000	12.5%	Codeine	300	100.0%
p-hydroxymethamphetamine	30000	3.3%	Hydrocodone	1500	20.0%
3,4-methylenedioxumethamphetamine (MDMA)	2000	50%	6-Monoacetylmorphine （6-MAN）	750	40.0%
3,4-Methylenedioxyethylamphetamine (MDEA)	50000	2%	Morphine 3-β -D-glucuronide	300	100.0%
Mephentermine	75000	1.3%	Ethylmorphine	100	300.0%
d-Amphetamine	50000	2%	Heroine	800	37.5%
L-Amphetamine	50000	2%	Levophenol	50000	0.6%
Ephedrine	100000	1%	Morphine3-glucuronide	400	75%
3,4-methylenedioxyampheta mine (MDA)	100000	10%	Norcodeine	16000	1.9%
Cocaine (COC)			Oxycodone	>75000	<0.4%
Benzoylecgonine	300	100%	Thebaine	>90000	<0.3%
Cocaine	800	37.5%			
Cocaethylene	12500	2.4%			
Ecgonine HCl	35000	0.9%			
Ecgonine	>50000	<0.6%			

8.2 Interference

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine or drug positive urine containing THC, COC, MET, MOP, MDMA with the concentration 50% below the cutoff and the concentration 50% above the cutoff, respectively. All potential interfering substances were added at a concentration of 100μg/mL (All concentrations of the drugs were confirmed with GC/MS). The urine specimens were tested with two lots of the corresponding Rapid Single/Multi-drug Test Cup and Test Dipcard. None of the compounds listed below were shown to interfere.

Acetaminophen	Estrone-3-sulfate	d,l-Octopamine
Acetophenetidin	Ethyl-p-aminobenzoate	Oxalic acid
Amoxicillin	Erythromycin	Oxolinic acid
Ampicillin	Fenoprofen	Oxymetazoline
Aspirin	Flucloxacillin	Oxytetracycline
Atenolol	Fluoxetine	Papaverine
Atorvastatin	Furosemide	Penicillin-G
Azlocillin	Gentisic acid	Pentazocine
Benzilic acid	Hemoglobin	Perphenazine
Benzylpenicillin	Hydralazine	Phenelzine
Benzoic acid	Hydrochlorothiazide	Prednisolone
Bilirubin	Hydrocortisone	Prednisone
Benzydamine	o-Hydroxyhippuric acid	d,l-Propanolol
Caffeine	p-Hydroxytyramine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Quinacrine
Cephalexin	Indomethacin	Quinine
Chloralhydrate	Iproniazid	Quindine
Chloramphenicol	d,l-Isoproterenol	Ranitidine

Chlorothiazide	Isoxsuprine	Salicylic acid
Chlorpheniramine	Ketamine	Serotonin
d,l-Chlorpromazine	Ketoprofen	Sulfamethazine
Cholesterol	Labetalol	Sulindac
Clonidine	Lisinopril	Tetracycline
Cimetidine	Loperamide	Tetrahydrozoline
Citalopram	Meperidine	Thiamine
Cortisone	Meprobamate	Thioridazine
Creatinine	Methoxyphenamine	d, l-Thyroxine
Deoxycorticosterone	Methylphenidate	Tolbutamine
Dexamethasone	Nadolol	Tolbutamide
Dextromethorphan	Nalidixic acid	Trifluoperazine
Diclofenac	Naproxen	Tryptamine
Diflunisal	Niacinamide	Uric acid
Digoxin	Nicotine	Verapamil
Diphenhydramine	Nifedipine	Zomepirac
Ephedrine	Norethindrone	
β-Estradiol	Noscapine	
Acetone	Acetylsalicylic acid	Albumin
Ascorbic Acid	Aspartame	Ascorbic Acid
Atropine	Benzocaine	Benzoylecgonine
Chlorquine	(±) Chlolrpheniramine	Creatine
Dexbrompheniramine	Dophenhydramine	Dopamine, (+/-)-Isoproterenol
1R,2S(+)-Ephedrine	Ethanol	Glucose
Guaiacol glyceryl ether	Levorphanol	Lidocaine
Lysergic acid	Methadone	Methanol
Methaqualone	Morphine	(1R,2S)-(-)-n-Methyl-ephedrine
(+)-Naproxen Nordiazepam	(+/-)-Norephedrine	Nortriptyline
Pheniramine	Phenothiazine	L-Phenylephrine
B-Phenylethylamin	Phencyclidine	Procaine
Propoxyphene	Ranitidine	Riboflavin
Salicylic acid	Secobarbital	Sodium Chloride
Theophyline	Tyramine	Uric acid
Vitamin(L-Ascorbic Acid)	4-Dimethylaminoantipyrine	d-Amphetamine

8.3 Effect of urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with each drug at 50% below and 50% above cutoff levels (All concentrations were confirmed with GC/MS). Each sample was tested by two lots of the corresponding Xenta Drug Screen Cup and Xenta Drug Screen Dipcard. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

8.4 Effect of Urinary specific gravity

The specific gravity studies were conducted on different specific gravity including 1.002,1.010, 1.020, 1.030, 1.040 specimens with drug free urine containing THC, COC, MET, MOP, MDMA at 50% below and 50% above cutoff level (All concentrations were confirmed with GC/MS). Each sample was tested by two lots of the corresponding Xenta Drug Screen Cup and Xenta Drug Screen Dipcard. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

8.5 Precision

Precision studies were performed using the single drug and multi-drug test formats. Drug free specimens were spiked with analytes at 0, ±75% cutoff, ±50% cutoff, ±25% cutoff and +100% cutoff of drug. The concentrations of the target drugs were confirmed with GC/MS. In both the single drug test and multi-drug test precision studies each concentration of the urine specimen was divided into aliquots. Each aliquot was blindly labeled by a nonparticipant. Separate sets of blinded coded samples were assigned and randomized prior to testing. The study was conducted by 6 operators at 3 Point-of-Care sites. Two operators per location tested 3 aliquots at each concentration for each lot per day (3 runs/day) for 10 non-consecutive days using one device lot per location. One operator tested the test dipcard format and the second operator tested the test cup format. There were 1620 observations by 3 sites at 9 concentrations.

Single drug Test Cup:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				Positive	Negative	Positive	Negative	Positive	Negative
COC	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	8	52	6	54	4	56
	300ng/ml	cutoff	60	36	24	34	26	38	22
	375ng/ml	+25%cutoff	60	56	4	54	6	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MET	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	4	56	8	52	6	54
	1000ng/ml	cutoff	60	34	26	36	24	38	22

	1250ng/ml	+25%cutoff	60	54	6	56	4	58	2
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MOP 300	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	8	52	10	50	8	52
	300ng/ml	cutoff	60	42	18	44	16	44	16
	375ng/ml	+25%cutoff	60	54	6	56	4	56	4
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
THC	0ng/ml	Negative	60	0	60	0	60	0	60
	12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	25ng/ml	-50%cutoff	60	0	60	0	60	0	60
	37.5ng/ml	-25%cutoff	60	8	52	6	54	6	54
	50ng/ml	cutoff	60	36	24	38	22	36	24
	62.5ng/ml	+25%cutoff	60	52	8	56	4	54	6
	75ng/ml	+50%cutoff	60	60	0	60	0	60	0
	87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
	100ng/ml	+100%cutoff	60	60	0	60	0	60	0
MDMA	0ng/ml	Negative	60	0	60	0	60	0	60
	125ng/ml	-75%cutoff	60	0	60	0	60	0	60
	250ng/ml	-50%cutoff	60	0	60	0	60	0	60
	375ng/ml	-25%cutoff	60	8	52	6	54	6	54
	500ng/ml	cutoff	60	36	24	34	26	36	24
	625ng/ml	+25%cutoff	60	52	8	54	6	56	4
	750ng/ml	+50%cutoff	60	60	0	60	0	60	0
	875ng/ml	+75%cutoff	60	60	0	60	0	60	0
	1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Multi-drug Test Cup:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				Positive	Negative	Positive	Negative	Positive	Negative
COC	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	8	52	6	54	4	56

	300ng/ml	cutoff	60	34	26	36	24	32	28
	375ng/ml	+25%cutoff	60	56	4	54	6	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MET	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	4	56	6	54	6	54
	1000ng/ml	cutoff	60	34	26	38	22	36	24
	1250ng/ml	+25%cutoff	60	56	4	58	2	58	2
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MOP 300	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	8	52	10	50	8	52
	300ng/ml	cutoff	60	42	18	40	20	44	16
	375ng/ml	+25%cutoff	60	54	6	56	4	56	4
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
THC	0ng/ml	Negative	60	0	60	0	60	0	60
	12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	25ng/ml	-50%cutoff	60	0	60	0	60	0	60
	37.5ng/ml	-25%cutoff	60	6	54	8	52	4	56
	50ng/ml	cutoff	60	38	22	36	24	36	24
	62.5ng/ml	+25%cutoff	60	52	8	56	4	54	6
	75ng/ml	+50%cutoff	60	60	0	60	0	60	0
	87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
	100ng/ml	+100%cutoff	60	60	0	60	0	60	0
MDMA	0ng/ml	Negative	60	0	60	0	60	0	60
	125ng/ml	-75%cutoff	60	0	60	0	60	0	60
	250ng/ml	-50%cutoff	60	0	60	0	60	0	60
	375ng/ml	-25%cutoff	60	8	52	10	50	6	54
	500ng/ml	cutoff	60	32	28	34	26	36	24
	625ng/ml	+25%cutoff	60	56	4	54	6	52	8

	750ng/ml	+50%cutoff	60	60	0	60	0	60	0
	875ng/ml	+75%cutoff	60	60	0	60	0	60	0
	1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Single drug Test Dipcard:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				Positive	Negative	Positive	Negative	Positive	Negative
COC	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	6	54	4	56	8	52
	300ng/ml	cutoff	60	34	26	36	24	34	26
	375ng/ml	+25%cutoff	60	54	6	56	4	56	4
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MET	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	4	56	4	56	6	54
	1000ng/ml	cutoff	60	36	24	34	26	34	26
	1250ng/ml	+25%cutoff	60	56	4	56	4	54	6
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MOP	0ng/ml	Negative	60	0	60	0	60	0	60
	500ng/ml	-75%cutoff	60	0	60	0	60	0	60
	1000ng/ml	-50%cutoff	60	0	60	0	60	0	60
	1500ng/ml	-25%cutoff	60	10	50	8	52	6	54
	2000ng/ml	cutoff	60	44	16	42	18	40	20
	2500ng/ml	+25%cutoff	60	56	4	54	6	54	6
	3000ng/ml	+50%cutoff	60	60	0	60	0	60	0
	3500ng/ml	+75%cutoff	60	60	0	60	0	60	0
	4000ng/ml	+100%cutoff	60	60	0	60	0	60	0
THC	0ng/ml	Negative	60	0	60	0	60	0	60
	12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	25ng/ml	-50%cutoff	60	0	60	0	60	0	60
	37.5ng/ml	-25%cutoff	60	6	54	4	56	8	52
	50ng/ml	cutoff	60	34	26	38	22	36	24
	62.5ng/ml	+25%cutoff	60	50	10	52	8	54	6
	75ng/ml	+50%cutoff	60	60	0	60	0	60	0

	87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
	100ng/ml	+100%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MDMA	0ng/ml	Negative	60	0	60	0	60	0	60
	125ng/ml	-75%cutoff	60	0	60	0	60	0	60
	250ng/ml	-50%cutoff	60	0	60	0	60	0	60
	375ng/ml	-25%cutoff	60	6	54	8	52	10	50
	500ng/ml	cutoff	60	34	26	36	24	32	28
	625ng/ml	+25%cutoff	60	54	6	56	4	52	8
	750ng/ml	+50%cutoff	60	60	0	60	0	60	0
	875ng/ml	+75%cutoff	60	60	0	60	0	60	0
	1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

Multi-drug Test Dipcard:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				Positive	Negative	Positive	Negative	Positive	Negative
COC	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	8	52	6	54	4	56
	300ng/ml	cutoff	60	34	26	36	24	32	28
	375ng/ml	+25%cutoff	60	56	4	54	6	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MET	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	6	54	8	52	4	56
	1000ng/ml	cutoff	60	38	22	36	24	36	24
	1250ng/ml	+25%cutoff	60	54	6	56	4	56	4
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MOP 300	0ng/ml	Negative	60	0	60	0	60	0	60
	500ng/ml	-75%cutoff	60	0	60	0	60	0	60
	1000ng/ml	-50%cutoff	60	0	60	0	60	0	60
	1500ng/ml	-25%cutoff	60	8	52	10	50	8	52

	2000ng/ml	cutoff	60	42	18	40	20	44	16
	2500ng/ml	+25%cutoff	60	54	6	56	4	56	4
	3000ng/ml	+50%cutoff	60	60	0	60	0	60	0
	3500ng/ml	+75%cutoff	60	60	0	60	0	60	0
	4000ng/ml	+100%cutoff	60	60	0	60	0	60	0
THC	0ng/ml	Negative	60	0	60	0	60	0	60
	12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	25ng/ml	-50%cutoff	60	0	60	0	60	0	60
	37.5ng/ml	-25%cutoff	60	8	52	4	56	6	54
	50ng/ml	cutoff	60	36	24	34	26	38	22
	62.5ng/ml	+25%cutoff	60	50	10	52	8	54	6
	75ng/ml	+50%cutoff	60	60	0	60	0	60	0
	87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
	100ng/ml	+100%cutoff	60	60	0	60	0	60	0
MDMA	0ng/ml	Negative	60	0	60	0	60	0	60
	125ng/ml	-75%cutoff	60	0	60	0	60	0	60
	250ng/ml	-50%cutoff	60	0	60	0	60	0	60
	375ng/ml	-25%cutoff	60	10	50	6	54	8	52
	500ng/ml	cutoff	60	36	24	34	26	34	26
	625ng/ml	+25%cutoff	60	52	8	56	4	54	6
	750ng/ml	+50%cutoff	60	60	0	60	0	60	0
	875ng/ml	+75%cutoff	60	60	0	60	0	60	0
	1000ng/ml	+100%cutoff	60	60	0	60	0	60	0

8.6 Accuracy

80 clinical urine specimens for each drug were analyzed by GC/MS and by two lots of the corresponding Single/Multi-drug Test Cup and Test Dipcard. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. All samples were blindly labeled by a nonparticipant. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing. The study was conducted by 4 nurses at two Point-of-Care sites. The test dipcard format was performed at one site and the test cup format at the second site. Each operator only performed one test format and different nurses tested each format. Results were as follows:

Single drug Test Cup:

Drug Test	Xenta Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
COC	+	0	0	0	5	35	80
	–	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	–	30	3	6	0	0	
MOP300	+	0	0	1	6	34	80
	–	30	4	5	0	0	
THC	+	0	0	0	6	33	80
	–	34	1	5	1	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	

Analysis of Discordant Results with Single drug Test Cup

Single drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
MET	1000	Positive	867	Methamphetamine
MOP300	300	Positive	275	Morphine
THC	50	Negative	61	11-nor-Δ9--THC-9-COOH
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine

Multi-drug Test Cup:

Drug Test	Xenta Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
COC	+	0	0	0	5	35	80
	-	33	1	6	0	0	
THC	+	0	0	0	6	33	80
	-	34	1	5	1	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	
MOP 300	+	0	0	1	6	34	80
	-	30	4	5	0	0	

Analysis of Discordant Results with Multi-drug Test Cup

Multi-drug Test Cup	GC/MS Analysis

Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
MET	1000	Positive	867	Methamphetamine
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MOP	300	Positive	275	Morphine
THC	50	Negative	61	11-nor-Δ9--THC-9-COOH

Single drug Test Dipcard:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
COC	+	0	0	0	5	35	80
	–	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	–	30	3	6	0	0	
MOP300	+	0	0	1	6	34	80
	–	30	4	5	0	0	
THC	+	0	0	0	6	33	80
	–	34	1	5	1	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	

Analysis of Discordant Results with Single drug Test Dipcard

Single drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
MET	1000	Positive	867	Methamphetamine
MOP300	300	Positive	275	Morphine
THC	50	Negative	61	11-nor-Δ9--THC-9-COOH
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine

Multi-drug Test Dipcard:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
COC	+	0	0	0	5	35	80
	–	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	–	30	3	6	0	0	

MOP300	+	0	0	1	6	34	80
	–	30	4	5	0	0	
THC	+	0	0	0	6	33	80
	–	34	1	5	1	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
	+	0	0	0	5	34	

Analysis of Discordant Results with Rapid Multi-drug Test Dipcard

Multi-drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
MET	1000	Positive	867	Methamphetamine
MOP300	300	Positive	275	Morphine
THC	50	Negative	61	11-nor-Δ9--THC-9-COOH
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine

9. Conclusion:

The data collected in the performance and accuracy studies demonstrate that the Xenta Drug Screen Cup and Xenta Drug Screen Dipcard are substantially equivalent to the predicate device.

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