510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K222955

B Applicant

Xenta Biomedical Science Co., Ltd.

C Proprietary and Established Names

Xenta Drug Screen Cup, Xenta Drug Screen Dipcard

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
DJC	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Cocaine, Marijuana, Methamphetamine, Morphine, Methylenedioxymethamphetamine

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:

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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not applicable; this is a visually read single use device

IV Device/System Characteristics:

A Device Description:

Xenta Drug Screen Cup and Xenta Drug Screen Dipcard are competitive binding, lateral flow immunochromatographic assays.

Kit Contents for Xenta Drug Screen Cup:

- One Xenta Drug Screen Cup with integrated test card.
- Desiccant Pouch.

Kit Contents for Xenta Drug Screen Dipcard:

- One pouch containing a test panel and desiccant.
- Urine Cups

The Xenta Drug Screen Cup and Xenta Drug Screen Dipcard formats use identical test strips made with the same chemical formulation and manufacturing procedures.

B Principle of Operation:

The candidate device is a competitive immunoassay. It is a chromatographic absorbent device in which drugs within a urine sample competitively bind to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is at a level below the detection level of the test, the respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored test line in the Test Region (T) of the strip, that, regardless of its intensity, indicates a negative test result. When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip (if the test has been performed properly).

V Substantial Equivalence Information:

A Predicate Device Name(s):

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

B Predicate 510(k) Number(s):

K153050

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222955	K153050
Device Trade Name	Xenta Drug Screen Cup and Xenta Drug Screen Dipcard	Rapid Single/Multi-drug Test Cup Rapid Single/Multi-drug Test Dipcard
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of drugs-of-abuse in urine	Same
Specimen	Urine	Same
Read Time	5 minutes	Same
Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Cutoff	Cocaine:300 ng/mL Methamphetamine:1000 ng/mL Morphine:300 ng/mL Marijuana:50 ng/mL Methylenedioxy-methamphetamine:500 ng/mL	Same
General Device Characteristic Differences		
Configuration	Dipcard and Cup	Cassette, Dipcard and Cup
Intended Users	Prescription Use Only	Over the Counter (OTC) Use and Prescription Use

VI Standards/Guidance Documents Referenced:

None.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were performed for the Xenta Drug Screen Dipcard and Xenta Drug Screen Cup formats. Drug free specimens were spiked with analytes at 0, ±75% cutoff, ±50% cutoff, ±25% cutoff, the cutoff, and +100% cutoff of each drug. The concentrations of the target drugs were confirmed with GC/MS. Each urine specimen was divided into aliquots. Testing was performed by an operator blinded to the sample concentration. Separate sets of blind-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 Xenta Drug Screen Dipcard format and the second operator tested the Xenta Drug Screen Cup format. Precision studies were performed using the single drug and multi-drug test formats and results were similar. Only the results from the multi-drug test format for both the screen cup and screen dipcard are provided in the tables below:

Multi-Drug Xenta Drug Screen Cup Precision Results:

Drug test	Approximate concentration	% of cutoff	Number of Determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				+	-	+	-	+	-
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
	0ng/ml	Negative	60	0	60	0	60	0	60

Drug test	Approximate concentration	% of cutoff	Number of Determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				+	-	+	-	+	-
THC	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

Multi-Drug Xenta Drug Screen Dipcard Precision Results:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				+	-	+	-	+	-
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

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				+	-	+	-	+	-
	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

2. Linearity:

   Not Applicable.

3. Analytical Specificity/Interference:

Cross-Reactivity

To determine cross-reactivity, drug metabolites and structurally similar compounds were tested. All the components were added to drug-free normal human urine. Each sample was tested in 5 replicates using two lots of Xenta Drug Screen Dipcard and one lot of Xenta Drug Screen Cup. 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 generated a negative result was reached. 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.

Compounds Tested	Lowest Concen. (ng/mL)	% Cross-reactivity	Compounds Tested	Lowest Concen. (ng/mL)	% Cross-reactivity
Cannabinoids (THC)			**Methylenedioxy-methamphetamine (MDMA)**		
11-nor-Δ9-THC-9-COOH	50	100%	(+/-)3,4-Methylenedioxy-methamphetamine (MDMA)	500	100%
11-nor-Δ8-THC-9-COOH	50	100%	3,4-methylenedioxyamphetamine (MDA)	2200	22.7%
Δ9-THC	15000	0.3%	3,4-Methylenedioxy-ethylamphetamine (MDEA)	240	208.3%
Δ8-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%

Compounds Tested	Lowest Concen. (ng/mL)	% Cross-reactivity	Compounds Tested	Lowest Concen. (ng/mL)	% Cross-reactivity
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%			
Benzoylecgonine	300	100%			
Cocaine	800	37.5%			

Interfering substances

To determine interference, potentially interfering compounds (listed below) were added to drug-free urine or drug positive urine containing MDMA, THC, COC, MET, and MOP concentrations 50% below the cutoff and 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 in 3 replicates with two lots of the rapid single/multi-drug Xenta Drug Screen Dipcard and one lot of the rapid single/multi-drug Xenta Drug Screen Cup. None of the urine samples showed any deviation from the expected results.

Acetaminophen, Acetophenetidin, Amoxicillin, Ampicillin, Aspirin, Atenolol, Atorvastatin, Azlocillin, Benzilic acid, Benzylpenicillin, Benzoic acid, Bilirubin, Benzydamine, Caffeine, Carbamazepine, Cephalexin, Chloralhydrate, Chloramphenicol, Chlorothiazide, Chlorpheniramine, d,l-Chlorpromazine, Cholesterol, Clonidine, Cimetidine,Citalopram, Cortisone, Creatinine , Deoxycorticosterone, Dexamethasone, Dextromethorphan, Diclofenac,Diflunisal, Digoxin, Diphenhydramine, β-Estradiol, Estrone-3-sulfate, Ethyl-p-aminobenzoate, Erythromycin, Fenoprofen, Flucloxacillin, Fluoxetine, Furosemide, Gentisic acid, Hemoglobin, Hydralazine, Hydrochlorothiazide,Hydrocortisone, o-Hydroxyhippuric acid, Ibuprofen,Indomethacin, Iproniazid, Isoxsuprine, Ketamine, Ketoprofen, Labetalol, Lisinopril, Loperamide, Meperidine, Meprobamate, Methoxyphenamine, Nadolol, Nalidixic acid, Naproxen, Niacinamide, Nicotine, Nifedipine, Norethindrone, Noscapine, d,l-Octopamine, Oxalic acid, Oxolinic acid, Oxymetazoline, Oxytetracycline, Papaverine, Penicillin-G, Pentazocine, Perphenazine, Phenelzine, Prednisolone, Prednisone, d,l-Propanolol, Quinacrine, Quinine, Quindine, Salicylic acid, Serotonin, Sulfamethazine, Sulindac, Tetracycline, Tetrahydrozoline, Thiamine, Thioridazine, d, l-Thyroxine, Tolbutamine, Tolbutamide, Trifluoperazine, Tryptamine, Uric acid, Verapamil, Zomepirac, 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, (+/-)-Norephedrine, Nortriptyline, Nordiazepam, 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

Effect of Urinary Specific Gravity
The specific gravity studies were conducted on drug-free urine specimens with varying specific gravity conditions including 1.002, 1.010, 1.020, 1.030, 1.040 spiked with MDMA, THC, COC, MET, or MOP at 50% below and 50% above cutoff levels. All concentrations were confirmed with GC/MS. Each sample was tested using two lots of the corresponding multi-drug Xenta Drug Screen Cup and Xenta Drug Screen Dipcard. The results demonstrate that the tested range of specific gravity does not affect the test result.

Effect of Urinary pH
The pH of an aliquot of negative urine pool was 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 using two lots of the corresponding multi-drug Xenta Drug Screen Cup and Xenta Drug Screen Dipcard. The result demonstrate that the tested pH range does not interfere with the performance of the test.

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 Cut-Off:

   Refer to Section VII.A.1

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Eighty (80) clinical urine specimens for each drug were analyzed by GC/MS and by two lots of the corresponding Xenta Drug Screen Cup and Xenta Drug Screen Dipcard. The study was conducted by 4 operators at two Point-of-Care sites in which the Xenta Drug Screen Cup or Xenta Drug Screen Dipcard format was tested. Comparison studies were performed using the single drug and multi-drug test formats and results were similar. Only the results from the multi-drug test format for both the Xenta Drug Screen cup and Xenta Drug Screen Dipcard are provided in the tables below:

Multi-Drug Xenta Drug Screen Cup Test Results

Drug Test	Xenta Result		Less than half the cutoff concentration	Near Cutoff Negative (Between	Near Cutoff Positive (Between the	High Positive (greater than	Total

		Drug free by GC/MS analysis	by GC/MS analysis	50% below the cutoff and the cutoff concentration)	cutoff and 50% above the cutoff concentration)	50% above the cutoff concentration)	
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 Xenta Drug Screen Cup

Multi-drug Xenta Drug Screen 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-Methylenedioxy-methamphetamine
MOP	300	Positive	275	Morphine
THC	50	Negative	61	11-nor-Δ9--THC-9-COOH

Multi-Drug Xenta Drug Screen Dipcard Test Results

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 Xenta Drug Screen Dipcard

Multi-drug Xenta Drug Screen Cup			GC/MS Analysis	
Drug Test	Cutoff (ng/mL)	Test Result	Drug Concentration	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

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
Five drug free specimens were spiked with the respective drug to concentrations of 0, -50% and +50% cutoff levels. The samples were tested in replicates of 10 with one lot of Xenta Drug Screen Cup and one lot of Xenta Drug Screen Dipcard following the procedures described in the package inserts. The sponsor provided data to support the recommendation for read time. The sponsor recommends that the test results should be read 5-30 minutes after use.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

Not Applicable.

VIII Proposed Labeling:

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

IX Conclusion:

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