510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

K130082

B. Purpose for Submission:

New Device

C. Measurand:

Amphetamine, Barbiturates, Cocaine, Marijuana, Methadone, Methamphetamine, Morphine, Oxycodone, Phencyclidine

D. Type of Test:

Qualitative immunochromatographic tests for drugs of abuse in urine

E. Applicant:

GenPrime Inc.

F. Proprietary and Established Names:

The GenPrime Drugs of Abuse (DOA) Reader System

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.3100, Amphetamine Test System
   21 CFR §862.3150, Barbiturate Test System
   21 CFR §862.3250, Cocaine and cocaine metabolite Test System
   21 CFR §862.3870, Cannabinoid Test System
   21 CFR §862.3620, Methadone Test System
   21 CFR §862.3610, Methamphetamine Test System
   21 CFR §862.3640, Morphine test system
   21 CFR §862.3650, Opiate Test System
   Phencyclidine, Unclassified
   21 CFR §862.2400, Densitometer/Scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use

2. Classification:
   Class II – for all except Phencyclidine and the Densitometer/Scanner
   Phencyclidine – Unclassified
   Densitometer/Scanner – Class I

3. Product code:
   DKZ, DIS, DIO, LDJ, DJR, DJC, DJG, LCM, DNK, JQT

4. Panel:
   Clinical Toxicology (91) and Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The GenPrime Drugs of Abuse (DOA) Reader System consists of the GenPrime DOA Reader, GenPrime DOA Windows®-compatible Software and compatible qualitative immunochromatographic, OS Cup and Split Key Cup (SK Cup) test devices. The GenPrime DOA Reader System is for *in vitro* diagnostic use and is intended for prescription use in laboratories, point-of-care, and workplaces by trained users. The test is not intended for over-the-counter use. The GenPrime DOA Reader System test devices cannot be read visually. The GenPrime DOA Reader and compatible DOA test devices qualitatively detect drug classes in human urine at the cutoff concentrations shown below:

OS Cup

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
BAR	Barbiturates (Secobarbital)	300 ng/mL
COC	Cocaine (Benzoylecgonine)	150 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

SK Cup

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
MTD	Methadone	300 ng/mL
MOP 300	Morphine	300 ng/mL
MOP 2000	Morphine	2000 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

Configurations of the OS Cup and SK cup may consist of any combination of the above listed drug analytes associated with the respective cup.

The GenPrime DOA reader system provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography / tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic prescription use in laboratories, point-of-care, and workplace sites

4. Special instrument requirements:

   The GenPrime DOA Reader

I. Device Description:

The GenPrime Drugs of Abuse (DOA) Reader System consists of a small, portable high resolution flatbed scanner, customized GenPrime DOA Reader Software, and lateral flow tests that are intended for use in the system. The scanner has a custom scanner lid with an opening for the test device, and a scanner stand, which places the scanner bed at the appropriate angle for running and reading the test devices. The system is intended for use with two test devices, the OS Cup and the Split Key Cup, both of which are rapid, single use, disposable immunochromatographic tests for the qualitative detection of drugs of abuse in human urine.

During analysis, an image of a compatible test device is captured and the software algorithm determines from the image whether the presence or absence of colored test lines is associated with a positive or negative result for each analyte on a test format. The software also confirms the validity of the results by verifying the presence of control lines.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   PROFILE®-V MEDTOXScan® Drugs of Abuse Test System

2. Predicate 510(k) number(s):

   K080635

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate (K080635)**
Intended Use	Determines qualitative positive or negative result from drugs of abuse immunoassay screens using an instrument reader	Same

Assay Type	Competitive assay where concentration of drug is inversely related to the visible signal detected by the instrument.	Same
System Procedure	Sample is added to a single use test device, which is then read by the instrument. The instrument is designed to read multiple single use test devices, one at a time.	Same

Differences		
Item	**Device**	**Predicate (K080635)**
Test Device Format	Cup	Cassette
Test Time and Timing Method	Operator manually times test development for 5 minutes and then operates the instrument.	Instrument internally times test strip development for 10 minutes and then scans the test cassette.
Detection Method	Measures density of visible lines against background on single-use test device.	Measures reflectance of visible lines on single use test cassette.
Cutoff values	BAR cutoff is 300ng MTD cutoff is 300ng	BAR cutoff is 200ng MTD cutoff is 200ng

K. Standard/Guidance Document Referenced (if applicable):

- ISO 14971:2007 Second Addition: Medical devices-Application of risk management to medical devices
- IEC 62304 First edition 2006-05, Medical device software – Software life cycle processes
- AAMI/ANSI/IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility -Requirements and Tests
- UL 60950-1, 1st Edition, 2006-07-07 Information Technology Equipment – Safety – Part 1: General Requirements
- CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance

L. Test Principle:

The GenPrime Drugs of Abuse (DOA) Reader System measures density of visible lines against background for two single-use immunochromatographic drug test formats: the OS Cup and the Split Key Cup. At the conclusion of the test (5 minutes for both the OS Cup and the Split Key Cup), the image of the device is captured by the scanner and the software algorithm determines from the image whether the presence or absence of colored test lines is associated with a positive or negative result for each analyte on a test format. The software also confirms the validity of the results by verifying the presence of control lines. The results are recorded and archived in a database along with an image of the test, patient and operator information and the time of image capture.

The OS Cup consists of a test card with drug strips integrated into a one-step urine cup. Each drug strip consists of: (1) a purple colored pad containing mouse monoclonal anti-drug antibodies conjugated with colloidal gold and rabbit IgG antibodies conjugated with colloidal gold, and (2) a nitrocellulose membrane strip containing 1-3 Test lines and a Control line. The Test line is coated with drug-protein conjugate and the Control line is coated with goat anti-rabbit IgG antibodies.

The Split Key Cup consists of a test card with drug strips integrated into a urine cup with a partition that requires a key activation step to disperse urine into the cup for testing to begin. Each drug strip consists of: (1) a purple colored pad containing mouse monoclonal anti-drug antibodies conjugated with colloidal gold and rabbit IgG antibodies conjugated with colloidal gold, and (2) a nitrocellulose membrane strip containing 1-3 Test lines and a Control line. The Test line is coated with drug-protein conjugate and the Control line is coated with goat anti-rabbit IgG antibodies.

For each cup, a line must form at the Control line position to indicate that sufficient sample was applied and that the reagents are migrating properly. If a Control line does not form, the test is invalid.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   The precision studies were performed at three sites representative of laboratory, workplace, and POC settings with a minimum of two operators per site. The operators performed the tests following the instructions for use, which are included with the GenPrime DOA Reader and with each test device intended for use with the GenPrime DOA Reader System.

   Precision studies were performed with the target analytes at 0%, 25%, 50%, 75%, 125%, 150%, 175%, and 200% of the cutoff during a 20 working day period using solutions containing drug concentrations confirmed by GC/MS. The identity of the samples was masked from the operator.

   Performance of the GenPrime DOA Reader was evaluated for each drug analyte by testing each drug at the stated concentration using a minimum of 10 tests per operator.

Results are shown below:

OS Cup, AMP (500 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	100	57	57	0	100%
50%	250	57	48	9	84.2%
75%	375	57	19	38	33.3%
125%	625	58	2	56	96.6%
150%	750	58	0	58	100%
175%	875	57	1	56	98.2%
200%	1000	57	0	57	100%

SK Cup, AMP (500 ng/mL)				
ng/mL	N	# NEG	# POS	Precision
0	86	86	0	100%
100	88	88	0	100%
250	84	78	6	92.9%
375	85	47	38	55.3%
625	84	3	81	96.4%
750	85	8	77	90.6%
875	87	2	85	97.7%
1000	89	0	89	100%

OS Cup, BAR (300 ng/mL)					
% of Cutoff	ng/mL	N	# NE	# POS	Precision
NEG	0	65	65	0	100%
25%	75	57	57	0	100%
50%	150	57	53	4	93.0%
75%	225	57	22	35	38.6%
125%	375	58	3	55	94.8%
150%	450	58	0	58	100%
175%	525	57	0	57	100%
200%	600	57	2	55	96.5%

SK Cup, MET (500 ng/mL)				
ng/mL	N	# NEG	# POS	Precision
0	86	86	0	100%
100	88	88	0	100%
250	84	81	3	96.4%
375	85	57	28	67.1%
625	84	4	80	95.2%
750	85	3	82	96.5%
875	87	0	87	100%
1000	89	2	87	97.8%

OS Cup, COC (150 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	37.5	57	57	0	100%
50%	75	57	43	14	75.4%
75%	112.5	57	14	43	24.6%
125%	187.5	58	1	57	98.3%
150%	225	58	0	58	100%
175%	262.5	57	0	57	100%
200%	300	57	0	57	100%

SK Cup, MTD (300 ng/mL)				
ng/mL	N	# NEG	# POS	Precision
0	86	86	0	100%
75	88	88	0	100%
150	84	83	1	98.8%
225	85	72	13	84.7%
375	84	10	74	88.1%
450	85	3	82	96.5%
525	87	0	87	100%
600	89	0	89	100%

OS Cup, MET (500 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	100	57	57	0	100%
50%	250	57	53	4	93.0%
75%	375	57	18	39	31.6%
125%	625	58	0	58	100%
150%	750	58	0	58	100%
175%	875	57	0	57	100%
200%	1000	57	0	57	100%

SK Cup, MOP (300 ng/mL)				
ng/mL	N	# NEG	# POS	Precision
0	86	86	0	100%
75	45	45	0	100%
150	45	43	2	95.6%
225	46	29	17	63.0%
375	45	4	41	91.1%
450	45	1	44	97.8%
525	45	0	45	100%
600	46	0	46	100%

OS Cup, THC (50 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	12.5	57	57	0	100%
50%	25	57	51	6	89.5%

SK Cup, MOP (2000 ng/mL)				
ng/mL	N	# NEG	# POS	Precision
0	86	86	0	100%
500	88	88	0	100%
1000	84	83	1	98.8%

75%	37	57	46	11	80.7%
125%	62	58	7	51	87.9%
150%	75	58	5	53	91.4%
175%	87.5	57	4	53	93.0%
200%	100	57	0	57	100%

1500	85	63	22	74.1%
2500	84	11	73	86.9%
3000	85	2	83	97.6%
3500	87	0	87	100%
4000	89	0	89	100%

SK Cup, OXY (100 ng/mL)				
ng/mL	**N**	**# NEG**	**# POS**	**Precision**
0	86	86	0	100%
25	88	88	0	100%
50	84	81	3	96.4%
75	85	57	28	67.1%
125	84	15	69	82.1%
150	85	12	73	85.9%
175	87	5	82	94.3%
200	89	1	88	98.9%
SK Cup, PCP (25 ng/mL)				
ng/mL	**N**	**# NEG**	**# POS**	**Precision**
0	86	86	0	100%
6.25	88	88	0	100%
12.5	84	81	3	96.4%
18.75	85	50	35	58.8%
31.25	84	6	78	92.9%
37.5	85	4	81	95.3%
43.75	87	0	87	100%
50	89	0	89	100%
SK Cup, THC (50 ng/mL)				
ng/mL	**N**	**# NEG**	**# POS**	**Precision**
0	86	86	0	100%
12.5	88	88	0	100%
25	84	82	2	97.6%
37	85	63	22	74.1%
62	84	14	70	83.3%
75	85	8	77	90.61%
87.5	87	5	82	94.3%
100	89	0	89	100%

The sponsor conducted several studies to determine the root cause of the poor performance demonstrated by some of the drug analytes in the precision study shown above. The root cause was identified to be a preservative contained in the original samples tested. To verify that the root cause was correctly identified, a supplemental study was conducted at two point of care sites using new samples that did not contain the interfering substance. Results from this testing compared to the results from the original precision study are shown in the tables below.

OS Cup			
Test (Cutoff)	**Solution (% of Cutoff)**	**Percent Agreement**	
		Original Precision Data (N≥57)	**Additional Testing N=30**
AMP (500)	50%	84.2%	100%
AMP (500)	150%	100%	100%
BAR (300)	50%	93.0%	100%
BAR (300)	150%	100%	100%
COC (150)	50%	75.4%	100%
COC (150)	150%	100%	100%
MET (500)	50%	93.0%	100%
MET (500)	150%	100%	100%
THC (50)	50%	89.5%	100%
THC (50)	150%	91.4%	100%
SK Cup			
Test (Cutoff)	**Solution (% of Cutoff)**	**Percent Agreement**	
		Original Precision Data (N≥57)	**Additional Testing N=30**
AMP(500)	50%	92.9%	100%
AMP(500)	150%	90.6%	100%
MET(500)	50%	96.4%	100%
MET(500)	150%	96.5%	100%
MTD (300)	50%	98.8%	100%
MTD (300)	150%	96.5%	100%
MOP (2000)	50%	98.8%	100%
MOP (2000)	150%	97.6%	100%
OXY (100)	50%	96.4%	100%
OXY (100)	150%	85.9%	100%
PCP(25)	50%	96.4%	100%
PCP(25)	150%	95.3%	100%
THC(50)	50%	97.6%	100%
THC(50)	150%	90.6%	100%

b. Linearity/assay reportable range:

Not applicable. This is a qualitative test.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The sponsor specifies in the labeling the quality control products that must be used with the device systems. The quality control products were previously cleared under k121122.

The sponsor states in the labeling: "Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls."

Stability
Accelerated and real time shelf-life studies were conducted. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims the following expiration

date for shelf-life stability: 12 months for both devices (OS Cup and SK Cup). Shelf-life studies are ongoing.

d. Detection limit:

Analytical performance of the device around the cutoff is described in the precision section M.1.a above.

e. Analytical specificity:

Analytical specificity studies were performed to determine whether drugs and drug metabolites within the same class of drugs or with similar molecular structures cross-react in the test systems. Reference standards for the various metabolites and compounds were prepared at 100 µg/mL in pooled negative human urine samples. Compounds that tested positive were serially diluted until a negative result was observed. Results shown are expressed as the minimum concentration producing a positive result in the indicated assay. A list of these compounds and their level of cross reactivity is shown below for each cup.

OS Cup Related Compounds and Cross-Reactants

Related Compound or Cross-Reactant	Result	% Cross Reactive
Amphetamines (AMP)(d-Amphetamine) 500 ng/mL		
3,4-Methylendioxyamphetamine (MDA)	Positive at 500 ng/mL	100%
Amphetamine (d,l)	Positive at 1000 ng/mL	50%
Phentermine	Positive at 2250 ng/mL	22%
b-Phenylethylamine (phenethylamine)	Positive at 50000 ng/mL	1%
3,4-methylenedioxy-N-ethylamphetamine-	Negative at 100000 ng/mL	N/A
Amphetamine (l)	Negative at 100000 ng/mL	N/A
(1R,2S)-(-)-Ephedrine	Negative at 100000 ng/mL	N/A
3,4-Methylenedioxymethamphetamine	Negative at 100000 ng/mL	N/A
Fenfluramine	Negative at 100000 ng/mL	N/A
Methamphetamine (d)	Negative at 100000 ng/mL	N/A
Methamphetamine (l)	Negative at 100000 ng/mL	N/A
Tryptamine	Negative at 100000 ng/mL	N/A
Tyramine	Negative at 100000 ng/mL	N/A
Barbiturate (BAR) (Secobarbital) (300 ng/mL)		
Butabarbital	Positive at 75 ng/mL	400%
Butethal	Positive at 250 ng/mL	120%
Pentobarbital	Positive at 250 ng/mL	120%
Phenobarbital	Positive at 250 ng/mL	120%
Aprobarbital	Positive at 400 ng/mL	75%
Barbital	Positive at 500 ng/mL	60%
Alphenal	Positive at 600 ng/mL	50%
Amobarbital	Positive at 850 ng/mL	35%
Cyclopentobarbital	Positive at 1500 ng/mL	20%
Allobarbital	Positive at 3500 ng/mL	9%
Butalbital	Positive at 11000 ng/mL	3%
Mephobarbital	Positive at 100000 ng/mL	0%
Barbituric Acid	Negative at 100000 ng/mL	N/A
Glutethimide	Negative at 100000 ng/mL	N/A
Hexobarbital	Negative at 100000 ng/mL	N/A
Phenytoin (diphenylhydantoin)	Negative at 100000 ng/mL	N/A
Thiopental	Negative at 100000 ng/mL	N/A

Cocaine (COC) (Benzoylecgonine) 150 ng/mL		
Cocaethylene	Positive at 4000 ng/mL	4%
Cocaine	Positive at 10000 ng/mL	2%
Ecgonine	Positive at 10000 ng/mL	2%
Ecgonine Methyl Ester	Negative at 100000 ng/mL	N/A
Methamphetamines (MET) (d-Methamphetamine) 500 ng/mL		
3,4-Methylenedioxymethamphetamine	Positive at 1250 ng/mL	40%
Methamphetamine (l)	Positive at 6000 ng/mL	8%
3,4-methylenedioxy-N-ethylamphetamine-	Positive at 25000 ng/mL	2%
b-Phenylethylamine (phenethylamine)	Positive at 25000 ng/mL	2%
p-Hydroxymethamphetamine	Positive at 25000 ng/mL	2%
Amphetamine (d)	Positive at 50000 ng/mL	1%
Chloroquine	Positive at 50000 ng/mL	1%
Mephentermine	Positive at 50000 ng/mL	1%
3,4-Methylendioxyamphetamine (MDA)	Negative at 100000 ng/mL	N/A
Amphetamine (d,l)	Negative at 100000 ng/mL	N/A
Amphetamine (l)	Negative at 100000 ng/mL	N/A
Ephedrine	Negative at 100000 ng/mL	N/A
Fenfluramine	Negative at 100000 ng/mL	N/A
Phenmetrazine	Negative at 100000 ng/mL	N/A
Phentermine	Negative at 100000 ng/mL	N/A
Phenylephrine (l)	Negative at 100000 ng/mL	N/A
Procaine	Negative at 100000 ng/mL	N/A
Tyramine	Negative at 100000 ng/mL	N/A
Marijuana (THC) (11-nor-D9-THC-9 COOH) 50 ng/mL		
11-nor-D8-THC-9 COOH	Positive at 50 ng/mL	100%
11-Hydroxy- Δ9-THC	Positive at 5000 ng/mL	1%
Cannabinol	Positive at 20000 ng/mL	0%
Δ9-THC	Negative at 100000 ng/mL	N/A
Cannabidiol	Negative at 100000 ng/mL	N/A
Δ8-THC	Negative at 100000 ng/mL	N/A

Split Key Cup Related Compounds and Cross-Reactants

Related Compound or Cross-Reactant	Result	% Cross Reactive
Amphetamines (AMP) (d-Amphetamine) 500 ng/mL		
Amphetamine (d,l)	Positive at 1000 ng/mL	50%
3,4-Methylendioxyamphetamine (MDA)	Positive at 4000 ng/mL	13%
b-Phenylethylamine (phenethylamine)	Positive at 25000 ng/mL	2%
3,4-methylenedioxy-N-ethylamphetamine-	Negative at 100000	1%
(1R,2S)-(-)-Ephedrine	Negative at 100000	N/A
3,4-Methylenedioxymethamphetamine	Negative at 100000	N/A
Amphetamine (l)	Negative at 100000	N/A
Fenfluramine	Negative at 100000	N/A
Methamphetamine (d)	Negative at 100000	N/A
Methamphetamine (l)	Negative at 100000	N/A
Phentermine	Negative at 100000	N/A
Tryptamine	Negative at 100000	N/A
Tyramine	Negative at 100000	N/A
Methamphetamines (MET) (d-Methamphetamine) 500 ng/mL		
3,4-Methylenedioxymethamphetamine	Positive at 1000 ng/mL	50%
Methamphetamine (l)	Positive at 5000 ng/mL	10%
p-Hydroxymethamphetamine	Positive at 15000 ng/mL	3%
b-Phenylethylamine (phenethylamine)	Positive at 50000 ng/mL	1%

Chloroquine	Positive at 50000 ng/mL	1%
Mephentermine	Positive at 50000 ng/mL	1%
3,4-Methylendioxyamphetamine (MDA)	Negative at 100000	N/A
3,4-methylenedioxy-N-ethylamphetamine-	Negative at 100000	N/A
Amphetamine (d,l)	Negative at 100000	N/A
Amphetamine (d)	Negative at 100000	N/A
Amphetamine (l)	Negative at 100000	N/A
Ephedrine	Negative at 100000	N/A
Fenfluramine	Negative at 100000	N/A
Phenmetrazine	Negative at 100000	N/A
Phentermine	Negative at 100000	N/A
Phenylephrine (l)	Negative at 100000	N/A
Procaine	Negative at 100000	N/A
Tyramine	Negative at 100000	N/A
Morphine 300 ng/mL		
Morphine 6-β-D-Glucuronide	Positive at 250 ng/mL	120%
6-Monoacetylmorphine (6-MAM)	Positive at 300 ng/mL	100%
Codeine	Positive at 300 ng/mL	100%
Diacetylmorphine	Positive at 500 ng/mL	60%
Dihydrocodeine	Positive at 2500 ng/mL	12%
Morphine 3-β-D-Glucuronide	Positive at 3000 ng/mL	10%
Ethylmorphine	Positive at 5000 ng/mL	6%
Hydromorphone	Positive at 10000 ng/mL	3%
Thebaine	Positive at 20000 ng/mL	2%
Hydrocodone	Positive at 25000 ng/mL	1%
Nalorphine	Positive at 50000 ng/mL	1%
Apomorphine	Negative at 100000	N/A
Levorphanol (tartrate dihydrate)	Negative at 100000	0%
Naloxone	Negative at 100000	N/A
Naltrexone	Negative at 100000	N/A
Norcodeine	Negative at 100000	N/A
Norhydrocodone	Negative at 100000	N/A
Normorphine	Negative at 100000	N/A
Noroxymorphone	Negative at 100000	N/A
Oxycodone	Negative at 100000	N/A
Oxymorphone	Negative at 100000	N/A
Procaine	Negative at 100000	N/A
Methadone (MTD) (Methadone) 300 ng/mL		
Buprenorphine (MTD Replacement)	Negative at 100000	N/A
EDDP (Primary Metabolite)	Negative at 100000	N/A
EMDP (Secondary Metabolite)	Negative at 100000	N/A
Morphine 2000 ng/mL		
Morphine 6-β-D-Glucuronide	Positive at 2500 ng/mL	80%
Nalorphine	Positive at 2500 ng/mL	80%
Codeine	Positive at 3000 ng/mL	67%
Hydromorphone	Positive at 4000 ng/mL	50%
6-Monoacetylmorphine (6-MAM)	Positive at 5000 ng/mL	40%
Dihydrocodeine	Positive at 5000 ng/mL	40%
Ethylmorphine	Positive at 5000 ng/mL	40%
Morphine 3-β-D-Glucuronide	Positive at 5000 ng/mL	40%
Normorphine	Positive at 10000 ng/mL	20%
Hydrocodone	Positive at 12500 ng/mL	16%
Diacetylmorphine	Positive at 15000 ng/mL	13%
Norcodeine	Positive at 15625 ng/mL	13%
Oxymorphone	Positive at 25000 ng/mL	8%
Thebaine	Positive at 25000 ng/mL	8%

Apomorphine	Negative at 100000	N/A
Levorphanol (tartrate dihydrate)	Negative at 100000	N/A
Naloxone	Negative at 100000	N/A
Naltrexone	Negative at 100000	N/A
Norhydrocodone	Negative at 100000	N/A
Noroxymorphone	Negative at 100000	N/A
Oxycodone	Negative at 100000	N/A
Procaine	Negative at 100000	N/A
Oxycodone (OXY) (Oxycodone) 100 ng/mL		
Oxymorphone	Positive at 400 ng/mL	25%
Noroxymorphone	Positive at 2500 ng/mL	4%
Hydrocodone	Positive at 12500 ng/mL	1%
Naloxone	Positive at 37500 ng/mL	0%
Hydromorphone	Positive at 50000 ng/mL	0%
Levorphanol	Positive at 50000 ng/mL	0%
Naltrexone	Positive at 50000 ng/mL	0%
Norhydrocodone	Positive at 50000 ng/mL	0%
6-Monoacetylmorphine	Negative at 100000	N/A
Apomorphine	Negative at 100000	N/A
Codeine	Negative at 100000	N/A
Diacetylmorphine	Negative at 100000	N/A
Dihydrocodeine	Negative at 100000	N/A
Ethylmorphine	Negative at 100000	N/A
Morphine	Negative at 100000	N/A
Morphine 3-β-D-Glucuronide	Negative at 100000	N/A
Morphine 6-β-D-Glucuronide	Negative at 100000	N/A
Nalorphine	Negative at 100000	N/A
Norcodeine	Negative at 100000	N/A
Normorphine	Negative at 100000	N/A
Thebaine	Negative at 100000	N/A
Phencyclidine (PCP) (Phencyclidine) 25 ng/mL		
4-Hydroxyphencyclidine	Positive at 1500 ng/mL	2%
Marijuana (THC) (11-Nor-9-carboxy-Δ9-THC) 50 ng/mL		
11-Hydroxy- Δ9-THC	Positive at 5000 ng/mL	1%
11-nor-D8-THC-9 COOH	Positive at 5000 ng/mL	1%
Cannabinol	Positive at 20000 ng/mL	0%
Cannabidiol	Negative at 100000	N/A
Δ8-THC	Negative at 100000	N/A
Δ9-THC	Negative at 100000	N/A

pH and Specific Gravity

The GenPrime DOA Reader System was assayed with pH values of 3.0, 4.0, 7.0 and 9.0. Each sample was assayed in triplicate. The pH samples were fortified with drug concentrations at 50% (negative) and 150% (positive) of cutoff. All pH samples gave negative results in the 50% of cutoff level for each drug, and all gave positive results at the 150% of cutoff level for each drug.

The GenPrime DOA Reader System was assayed in triplicate with samples with specific gravity values of 1.003, 1.015 and 1.030. The specific gravity samples were fortified with drug concentrations as described above for pH. All specific gravity samples gave negative results in the 50% of cutoff level for each drug, and all gave positive results at the 150% of cutoff level for each drug.

Common Drugs

Drug free urine samples were spiked with drug concentrations that were at 50% (negative) and 150% (positive) of cutoff. Concentrations of 100,000 ng/mL of the

common drugs were then added to the preparation and assayed by the GenPrime DOA Reader System. None of the common drugs listed in the following table affected the expected results for the OS Cup or the Split Key Cup.

Common Drugs Evaluated with the OS Cup with the GenPrime DOA Reader System

Acetylsalicylic Acid	Chlorpheniramine	Morphine
Acetaminophen	Cocaine - COC	Phenobarbital – BAR
Brompheniramine maleate	Dextromethorphan	Phenytoin (Diphenylhydantoin) –
Caffeine	Doxylamine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Salicylic Acid

Common Drugs Evaluated with the Split Key Cup with the GenPrime DOA Reader System

Acetylsalicylic Acid	Chlorpheniramine	Morphine
Acetaminophen	Cocaine - COC	Phenobarbital – BAR
Brompheniramine maleate	Dextromethorphan	Phenytoin (Diphenylhydantoin) –
Caffeine	Doxylamine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Salicylic Acid

f. Assay cut-off:

Characterization of how the device performs around the claimed cutoff concentration appears in the precision section M.1.a. above.

2. Comparison studies:

a. Method comparison with predicate device:

The accuracy of the GenPrime DOA Reader System was evaluated at three sites representative of laboratory, workplace, and POC settings with blind coded clinical urine samples that contained varying concentrations of drugs as determined by GC/MS or LC/MS/MS. Results summaries are provided below for the OS Cup and for the Split Key Cup, for all sites combined.

Summary of method comparison data for the OS Cup (all sites combined)

DRUG (cutoff)	GenPrime Test System OS Cup	No Drug	Negative (Less than -50% cutoff)	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (Between cutoff and +50%)	Positive (greater than +50%)	GenPrime OS Cup Agreement with Reference
AMP (500)	Positive	0	0	3	5	36	100%
	Negative	40	1	4	0	0	93.8%
BAR (300)	Positive	0	0	3	4	36	100%
	Negative	40	11	1	0	0	94.5%
COC (150)	Positive	0	0	3	4	38	100%
	Negative	40	0	1	0	0	93.2%
MET (500)	Positive	0	0	2	4	36	100%
	Negative	40	8	2	0	0	96.2%

THC (50)	Positive	0	0	0	4	36	100%
	Negative	40	0	4	0	0	100%

Discordant Results for the OS Cup

Cutoff Value (ng/mL)	**Drug**	**GenPrime DOA Reader System**	**GC/MS or LC/MS/MS Value**
500	AMP	Presumptive Positive	Amphetamine at 306 ng/mL
	AMP	Presumptive Positive	Amphetamine at 437 ng/mL
	AMP	Presumptive Positive	Amphetamine at 370 ng/mL
300	BAR	Presumptive Positive	Phenobarbital at 210 ng/mL (=252 ng/mL BAR equiv)
	BAR	Presumptive Positive	Butalbital at 6000 ng/mL (=240 ng/mL BAR equiv)
	BAR	Presumptive Positive	Butalbital at 4644 ng/mL (=186 ng/mL BAR equiv)
150	COC	Presumptive Positive	Benzoylecgonine at 130 ng/mL
	COC	Presumptive Positive	Benzoylecgonine at 110 ng/mL
	COC	Presumptive Positive	Benzoylecgonine at 126 ng/mL
500	MET	Presumptive Positive	Methamphetamine at 264 ng/mL
	MET	Presumptive Positive	Methamphetamine at 277 ng/mL

Summary of method comparison data for the Split Key Cup (all sites combined)

DRUG (cutoff)	GenPrime Test System Split Key Cup	No Drug	Negative (Less than -50% cutoff)	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (Between cutoff and +50%)	Positive (greater than +50%)	GenPrime Split Key Cup Agreement with Reference
AMP (500)	Positive	0	0	4	4	36	100%
	Negative	40	1	4	0	0	91.8%
MET (500)	Positive	0	0	1	4	36	100%
	Negative	40	0	3	0	0	97.7%
MTD (300)	Positive	0	0	0	4	36	100%
	Negative	40	0	4	0	0	100%
MOP (300)	Positive	0	0	1	3	36	97.5%
	Negative	40	0	3	1	0	97.7%
MOP (2000)	Positive	0	1	2	4	36	100%
	Negative	40	0	3	0	0	93.5%
OXY (100)	Positive	0	0	2	4	36	100%
	Negative	40	0	2	0	0	95.45%
PCP (25)	Positive	0	0	0	3	39	97.7%
	Negative	40	17	4	1	0	100%
THC (50)	Positive	0	2	0	3	38	100%
	Negative	40	31	8	0	0	97.5%

Discordant Results for the Split Key Cup

Cutoff Value (ng/mL	Drug	GenPrime DOA Reader	GC/MS or LC/MS/MS Value
500	AMP	Presumptive Positive	Amphetamine at 250 ng/mL
	AMP	Presumptive Positive	Amphetamine at 437 ng/mL
	AMP	Presumptive Positive	Amphetamine at 365 ng/mL
	AMP	Presumptive Positive	Amphetamine at 370 ng/mL
500	MET	Presumptive Positive	Amphetamine at 307 ng/mL
300	MOP	Negative	Codeine at 333 ng/mL (=333 ng/mL MOP equiv)
	MOP	Presumptive Positive	Codeine at 283 ng/mL (=283 ng/mL MOP equiv)
2000	MOP	Presumptive Positive	Morphine at 377 ng/mL, Codeine at 2097 ng/mL (=1782 MOP equiv)
	MOP	Presumptive Positive	Morphine at 962 ng/mL, Codeine at 1437 ng/mL (=1925 MOP equiv)
	MOP	Presumptive Positive	Morphine at 843 ng/mL, Codeine at 328 ng/mL (=893 MOP equiv)
100	OXY	Presumptive Positive	Oxycodone at 65 ng/mL
	OXY	Presumptive Positive	Oxycodone at 50 ng/mL
25	PCP	Negative	Phencyclidine at 35 ng/mL
50	THC	Presumptive Positive	11-nor-9-carboxy-D9-THC at 22 ng/mL
	THC	Presumptive Positive	11-nor-9-carboxy-D9-THC at 24 ng/mL

A second study was submitted by the sponsor to support discrepant resolution of the discordant results obtained in the original method comparison studies for OPI and THC analytes for the SK Cup at the less than -50% cutoff level. Clinical specimens with OPI and THC concentrations at 0%-50% of the cutoff were tested in-house using the SK Cup with the GenPrime DOA Reader System and compared to GC/MS values. The results are below.

Additional of method comparison data for the Split Key Cup

DRUG (cutoff)	**GenPrime Test System Split Key Cup**	**Near Cutoff Negative (between -50% and cutoff)**	**GenPrime Split Key Cup Agreement with Reference**
MOP (2000 ng/mL)	Positive	0	100%
	Negative	112	100%
THC (50 ng/mL)	Positive	0	100%
	Negative	120	100%

b. Matrix comparison:

Not applicable. The assay is intended for use with urine samples only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Instrument Name:

GenPrime Drugs of Abuse Reader

O. System Descriptions:

1. Modes of Operation:

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes _X_____ or No _____

3. Specimen Identification:
   There is no sample identification function with this device. Samples are applied directly to the OS Cup or the Split Key Cup.

4. Specimen Sampling and Handling:
   This device is intended to be used with urine samples. The labeling provides instructions for storage of samples.

5. Calibration:
   Factory Calibrated

6. Quality Control:

   The sponsor specifies in the labeling the quality control products that must be used with the device systems. The quality control products were previously cleared under k121122.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

None

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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