

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k122809

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Methamphetamine, Barbiturates, Benzodiazepine, Opiate, Cannabinoids, Cocaine, Methadone, Tricyclic antidepressants, Buprenorphine, EDDP, MDMA, Morphine, Oxycodone, Phencyclidine and Propoxyphene

D. Type of Test:

Qualitative lateral flow immunochromatographic competitive binding assay

E. Applicant:

Advin Biotech

F. Proprietary and Established Names:

Advin Multi-Drug Screen Test Cassette

Advin Multi-Drug Screen Test Dip Card

Advin Multi-Drug Screen Test Cup

G. Regulatory Information:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
DKZ	II	862.3100, Amphetamine test system	Toxicology - 91
DJC	II	862.3610, Methamphetamine test system	Toxicology - 91
DIS	II	862.3150, Barbiturate test system	Toxicology - 91

JXM	II	862.3170, Benzodiazepine test system	Toxicology - 91
DJG	II	862.3650, Opiate test system	Toxicology - 91
LDJ	II	862.3870, Cannabinoid test system	Toxicology - 91
DIO	II	862.3250, Cocaine and cocaine metabolite test system	Toxicology - 91
DJR	II	862.3620, Methadone test system	Toxicology - 91
LFG	II	862.3910, Tricyclic antidepressant drug test system	Toxicology - 91
JXN	II	862.3700, Propoxyphene test system	Toxicology - 91
LCM	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology - 91

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The Advin Multi-Drug Screen Test is a one-step immunoassay for the qualitative detection of multiple drugs of abuse and/or their metabolites in human urine at the following cutoff levels:

Drug Test	Calibrator	Cutoff Level
Amphetamine (AMP)	d-Amphetamine	500 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoyllecgonine	150 ng/mL
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
Ecstasy (MDMA)	Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	500 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Morphine (MOR300)	Morphine	300 ng/mL
Opiates (OPI)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic-antidepressant (TCA)	Nortriptyline	1000 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50 ng/mL

The Advin Multi-Drug Screen Test consists of three formats: a Cassette, a Dip Card and a Cup, which may be configured in any combination of the drug analytes listed in the above table.

Advin Multi-Drug Screen Test is used to obtain a visual, qualitative, preliminary test result for prescription use in point of care sites, laboratory settings, and is also intended for workplaces and over-the-counter use. The Propoxyphene test strip is not intended for over-the-counter use.

The Advin Multi-Drug Screen Test will yield preliminary positive results when prescription drugs TCA, Barbiturates and Benzodiazepine, Methadone, Buprenorphine and Opiates are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for TCA, Barbiturates and Benzodiazepine in urine.

The Advin Multi-Drug Screen Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry/Mass (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

3. Special conditions for use statement(s):

This assay is intended for prescription use and over the counter use

4. Special instrument requirements:

Not applicable; this is a visually read single use device

I. Device Description:

The Advin Multi-Drug Screen Test consists of multi-drug test strips with one or two drug tests on each strip. Each of the two-drug test strips detects two drugs. Each two-drug test strip can also be formulated into two 1-drug test strip, where each test strip only detects one drug. The Advin Multi-Drug Screen Test has three types of test formats: a Cassette, a Dip Card and a Cup. All three formats use identical test strips made with same chemical formulation and manufacturing procedures.

The differences between the test formats are that (1) the Cassette format has a plastic cassette to hold the test strip; urine sample can be applied onto the sample well; (2) the Dip Card has a plastic card to hold the strips for dipping and a cap to expose the sample pads; and (3) the Cup format has an integrated cup with lid to hold the strips.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Innovacon Spectrum II Test Card and Test Card with Integrated Test Cup

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

k061718

3. Comparison with predicate:

Similarities/Differences		
Item	Device	Predicate
Intended Use	A rapid chromatographic immunoassay for the qualitative detection of multiple drugs/metabolites in human urine	Same
Sample Type	Urine	Same
Materials provided	Test devices (Cassette , Dipcard, Cup) and Package insert	Test Device (Test card, Cup) and Package insert
Cutoff concentrations (ng/mL)	Amphetamine 500 Barbiturates 300 Benzodiazepines 300 Buprenorphine 10 Cocaine 150 Methadone 300 MDMA 500 THC 50 Methamphetamine 500 morphine 300, or opiates 2,000 Oxycodone 100 Phencyclidine 25 Propoxyphene 300 Tricyclic antidepressants 1,000, EDDP 300	Amphetamine 1000 or 300 Barbiturates 300 Benzodiazepines 300 Buprenorphine 10 Cocaine 150 or 300 Methadone 300 MDMA 500 THC 50 Methamphetamine 500 or 1,000 morphine 300, or opiates 2,000 Oxycodone 100 Phencyclidine 25 Propoxyphene 300 Tricyclic antidepressants 1,000 EDDP 300
Methodology	Membrane Particle Assay	Same
Test time	5 minutes	Same
Format	Immunoassay	Same

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

- EN ISO13485, Medical devices – quality management systems – Requirements for regulatory purpose
- EN ISO14971, Medical device – application of risk management to medical device
- EN ISO14155-2, Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans

L. Test Principle:

The Advin Multi-Drug Screen Test is a lateral flow immunochromatographic competitive binding assay and is intended for prescription, workplace and OTC use. It is used as *in vitro* diagnostic to visually and qualitatively detect some of the most common drugs of abuse and/or their metabolites in human urine specimens. The test is based on the principle of competitive binding antigen-antibody immunochemistry. Urine migrates via capillary action along the nitrocellulose (NC) membrane strip pre-coated with a drug-protein conjugate band on the test line region and a colored antibody-colloidal gold conjugate pad, and rehydrates the antibody colloidal gold conjugate on test strip. This urine-gold conjugate mixture then migrates along the NC membrane to the immobilized drug-protein band. When a drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible color line on the test region. A drug-positive urine specimen will not generate a colored-line in the designated test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of urine specimen has been added and membrane wicking has occurred. These visual read tests are performed without the use of an instrument.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision of the device was characterized at three Physician's Lab Office (POL) sites using office personnel of varying educational backgrounds and laboratory experience. Several samples were prepared for this study using drug-free urine specimens collected and pooled from volunteers. Drug standards were spiked into the drug-free urine to the following drug concentrations: 0% cutoff, -50% cutoff, -25% cutoff, at cutoff, +25% cutoff and +50% cutoff. Each concentration was confirmed with GC/MS. Each sample was analyzed in 10 replicates by each of the testing personnel at each POL site, using each of the three assay formats. Results are presented below for each test format.

Cassette

Drug	Result	Drug concentration					
		Negative	-50%	-25%	Cutoff	+25%	+50%
AMP 500 ng/ml	Neg	60	60	42	13	8	0
	Pos	0	0	18	47	52	60
	Total	60	60	60	60	60	60
MOR 300 ng/ml	Neg	30	30	22	8	8	0
	Pos	0	0	8	22	22	30
	Total	30	30	30	30	30	30
COC 150 ng/ml	Neg	30	30	22	6	4	0
	Pos	0	0	8	24	26	30
	Total	30	30	30	30	30	30
THC 50 ng/mL	Neg	30	30	22	5	3	0
	Pos	0	0	8	25	27	30
	Total	30	30	30	30	30	30
MET 500 ng/mL	Neg	30	30	21	8	6	0
	Pos	0	0	9	22	24	30
	Total	30	30	30	30	30	30
PCP 25 ng/mL	Neg	30	30	23	6	5	0
	Pos	0	0	7	24	25	30
	Total	30	30	30	30	30	30
Barb 300 ng/mL	Neg	30	30	21	6	5	0
	Pos	0	0	9	24	25	30
	Total	30	30	30	30	30	30
BZO 300 ng/mL	Neg	30	30	23	8	4	0
	Pos	0	0	7	22	26	30
	Total	30	30	30	30	30	30
PPX 300 ng/mL	Neg	30	30	22	4	5	0
	Pos	0	0	8	26	25	30
	Total	30	30	30	30	30	30
BUP 10 ng/mL	Neg	30	30	24	5	5	0
	Pos	0	0	6	25	25	30
	Total	30	30	30	30	30	30
EDDP 300 ng/mL	Neg	30	30	22	8	9	0
	Pos	0	0	8	22	21	30
	Total	30	30	30	30	30	30
MTD 300 ng/mL	Neg	30	30	21	7	6	0
	Pos	0	0	9	23	24	30
	Total	30	30	30	30	30	30
TCA 1000 ng/mL	Neg	30	30	22	5	4	0
	Pos	0	0	8	25	26	30
	Total	30	30	30	30	30	30
OPI 2000 ng/mL	Neg	30	30	25	7	7	0
	Pos	0	0	5	23	23	30
	Total	30	30	30	30	30	30

MDMA 500 ng/mL	Neg	30	30	22	5	7	0
	Pos	0	0	8	25	23	30
	Total	30	30	30	30	30	30
OXY 100 ng/ml	Neg	30	30	21	7	4	0
	Pos	0	0	9	23	26	30
	Total	30	30	30	30	30	30

Dip card

Drug	Result	Drug concentration					
		Negative	-50%	-25%	Cutoff	+25%	+50%
AMP 500 ng/ml	Neg	60	60	45	14	11	0
	Pos	0	0	15	46	49	60
	Total	60	60	60	60	60	60
MOR 300 ng/ml	Neg	30	30	23	8	8	0
	Pos	0	0	7	22	22	30
	Total	30	30	30	30	30	30
COC 150 ng/ml	Neg	30	30	21	8	5	0
	Pos	0	0	9	22	25	30
	Total	30	30	30	30	30	30
THC 50 ng/mL	Neg	30	30	23	5	4	0
	Pos	0	0	7	25	26	30
	Total	30	30	30	30	30	30
MET 500 ng/mL	Neg	30	30	22	8	4	0
	Pos	0	0	8	22	26	30
	Total	30	30	30	30	30	30
PCP 25 ng/mL	Neg	30	30	24	6	6	0
	Pos	0	0	6	24	24	30
	Total	30	30	30	30	30	30
Barb 300 ng/mL	Neg	30	30	23	6	5	0
	Pos	0	0	7	24	25	30
	Total	30	30	30	30	30	30
BZO 300 ng/mL	Neg	30	30	23	7	4	0
	Pos	0	0	7	23	26	30
	Total	30	30	30	30	30	30
PPX 300 ng/mL	Neg	30	30	22	4	7	0
	Pos	0	0	8	26	23	30
	Total	30	30	30	30	30	30
BUP 10 ng/mL	Neg	30	30	23	5	6	0
	Pos	0	0	7	25	24	30
	Total	30	30	30	30	30	30
EDDP 300 ng/mL	Neg	30	30	23	9	8	0
	Pos	0	0	4	21	22	30
	Total	30	30	30	30	30	30

MTD 300 ng/mL	Neg	30	30	21	8	5	0
	Pos	0	0	9	22	25	30
	Total	30	30	30	30	30	30
TCA 1000 ng/mL	Neg	30	30	21	5	4	0
	Pos	0	0	9	25	26	30
	Total	30	30	30	30	30	30
OPI 2000 ng/mL	Neg	30	30	23	7	5	0
	Pos	0	0	7	23	25	30
	Total	30	30	30	30	30	30
MDMA 500 ng/mL	Neg	30	30	25	6	8	0
	Pos	0	0	5	24	22	30
	Total	30	30	30	30	30	30
OXY 100 ng/ml	Neg	30	30	22	8	3	0
	Pos	0	0	8	22	27	30
	Total	30	30	30	30	30	30

Cup

Drug	Result	Drug concentration					
		Negative	-50%	-25%	Cutoff	+25%	+50%
AMP 500 ng/ml	Neg	120	120	82	33	25	0
	Pos	0	0	38	87	95	120
	Total	120	120	120	120	120	60
MOR 300 ng/ml	Neg	60	30	24	9	8	0
	Pos	0	0	6	21	22	30
	Total	60	30	30	30	30	30
COC 150 ng/ml	Neg	210	30	21	9	6	0
	Pos	0	0	9	21	24	30
	Total	210	30	30	30	30	30
THC 50 ng/mL	Neg	210	30	24	4	4	0
	Pos	0	0	6	26	26	30
	Total	210	30	30	30	30	30
MET 500 ng/mL	Neg	210	30	21	9	6	0
	Pos	0	0	9	21	24	30
	Total	210	30	30	30	30	30
PCP 25 ng/mL	Neg	210	30	26	6	6	0
	Pos	0	0	4	24	24	30
	Total	210	30	30	30	30	30
Barb 300 ng/mL	Neg	210	30	21	6	8	0
	Pos	0	0	9	24	22	30
	Total	210	30	30	30	30	30
BZO 300 ng/mL	Neg	210	30	26	8	4	0
	Pos	0	0	4	22	26	30
	Total	210	30	30	30	30	30
PPX	Neg	210	30	20	4	6	0

300 ng/mL	Pos	0	0	10	26	24	30
	Total	210	30	30	30	30	30
BUP 10 ng/mL	Neg	210	30	22	4	6	0
	Pos	0	0	8	26	24	30
	Total	210	30	30	30	30	30
EDDP 300 ng/mL	Neg	210	30	24	9	9	0
	Pos	0	0	6	21	21	30
	Total	210	30	30	30	30	30
MTD 300 ng/mL	Neg	210	30	21	9	6	0
	Pos	0	0	9	21	24	30
	Total	210	30	30	30	30	30
TCA 1000 ng/mL	Neg	210	30	26	6	4	0
	Pos	0	0	6	24	26	30
	Total	210	30	30	30	30	30
OPI 2000 ng/mL	Neg	60	30	26	7	7	0
	Pos	0	0	4	23	23	30
	Total	60	30	30	30	30	30
MDMA 500 ng/mL	Neg	210	30	22	6	9	0
	Pos	0	0	8	24	21	30
	Total	210	30	30	30	30	30
OXY 100 ng/ml	Neg	210	30	24	9	4	0
	Pos	0	0	6	21	26	30
	Total	210	30	30	30	30	30

b. Linearity/assay reportable range:

Not applicable. The assays are intended for qualitative use.

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

External control standards are not supplied with this device; however, this device has internal process controls. A colored line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are informed that the test is invalid if a line fails to appear in the control region.

Stability

Accelerated and real time studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date: The Advin Multi-Drug Screen Test unopened (shelf-life) stability is 24 months for all formats (cassette, cup and dip card).

d. Detection limit:

Not applicable. The assay is intended for qualitative use.

e. Analytical specificity:

Cross Reactivity Study:

Each compound was tested for cross reactivity with certain compounds, drugs, and drug metabolites. Each compound was spiked to drug-free urine to 100µg/mL. Each sample was tested in 3 replicates. If any positive result was observed, the compound, drug/drug metabolites were further diluted sequentially to different concentrations and tested in triplicates until the highest concentration that generates negative result. The cross reacting substances with the lowest concentration that produces a positive result was identified and are presented in the product package insert. Results are shown below.

Amphetamine

Compound	Concentration (ng/mL)	% Cross-reactivity
d-Amphetamine	500	100%
L-amphetamine	50,000	1%
MDA	8,000	6.5%
Phentermine	45,000	1.1%

Cocaine

Compound	Concentration (ng/mL)	% Cross-reactivity
Benzoylcegonine	150	100%
Cocaine	5,000	3%
Cocaethylene	50,000	0.3%
Ecgonine	50,000	0.3%

Methamphetamine

Compound	Concentration (ng/mL)	% Cross-reactivity
d-Methamphetamine	500	100%
Ephedrine	100,000	0.5%
MDEA	30,000	1.7%
MDMA	3,500	14.3%
Mephentermine	75,000	0.7%
d-Amphetamine	50,000	1%
L-Amphetamine	50,000	1%

Morphine

Compound	Concentration (ng/mL)	% Cross-reactivity
Morphine	300	100%
Codeine	100	300%
Ethylmorphine	100	300%
Heroin	800	37.5%
Hydrocodone	1,250	24%

Hydromorphone	2,500	12%
Levophenol	50,000	0.6%
Morphine3-glucuronide	400	75%
Norcodeine	16,000	1.9%
Oxycodone	75,000	0.4%
Thebaine	90,000	0.3%

Opiate

Compound	Concentration (ng/mL)	% Cross-reactivity
Morphine	2,000	100%
Oxycodone	70,000	2.9%
Codeine	1,800	111.1%
Morphine3-glucuronide	2,600	76.9%
Ethylmorphine	1,500	133.3%
Hydrocodone	5,000	40%
Hydromorphone	5,000	40% %
Thebaine	95,000	2.1%
Heroin	11,000	18.2%

PCP

Compound	Concentration (ng/mL)	% Cross-reactivity
Phencyclidine	25	100%
4-hydroxy-PCP	1,500	1.7%

THC

Compound	Concentration (ng/mL)	% Cross-reactivity
11-nor- Δ^9 -THC-9-COOH	50	100%
(+/-)11-hydroxy- Δ^9 -THC	5,000	1%
(-)- Δ^8 -THC	20,000	0.3%
(-)- Δ^9 -THC	20,000	0.3%

MDMA

Compound	Concentration (ng/mL)	% Cross-reactivity
(+/-)-MDMA	500	100%
(+/-)-MDA	3,900	12.8%
(+/-)-MDEA	500	100%

Buprenorphine

Compound	Concentration (ng/mL)	% Cross-reactivity
Buprenorphine	10	100%

Oxycodone

Compound	Concentration (ng/mL)	% Cross-reactivity
Oxycodone	100	100%
Hydromorphone	25,000	0.4%
Hydrocodone	5,000	2%
Oxymorphone	12,500	0.8%
Ethymorphine	50,000	0.2%
Codeine	50,000	0.2%

Benzodiazepines

Compound	Concentration (ng/mL)	% Cross-reactivity
Oxazepam	300	100%
Alpha-hydroxyalprazolam	1,900	15.8%
Alprazolam	200	150%
Bromazepam	1,000	30%
Clobazam	200	150%
Clorazepam	750	40%
Desalkylflurazepam	1,200	25%
Diazepam	1,000	30%
Flunitrazepam	250	120%
Lorazepam	3,900	7.7%
Lorazepam-glucuronide	5,000	6%
Nitrazepam	250	120%
Nordiazepam	390	76.9%
Norchlordiazepapoxide	500	60%
Nordiazepoxide	400	75%
Temazepam	150	200%
Triazolam	2,500	12%

Barbiturates

Compound	Concentration (ng/mL)	% Cross-reactivity
Secobarbital	300	100%
Amorbarbital	2,500	12%
Aprobarbital	500	60%
Butabarbital	100	300%
Butalbital	300	100%
Cyclopentobarbital	500	60%
Phenobarbital	300	100%
Phentobarbital	250	120%

Methadone

Compound	Concentration (ng/mL)	% Cross-reactivity
Methadone	300	100%

EDDP

Compound	Concentration (ng/mL)	% Cross-reactivity
EDDP	300	100%

TCA

Compound	Concentration (ng/mL)	% Cross-reactivity
Nortriptyline	1,000	100%
Amitriptyline	4,000	25%
Clomipramine	2,000	50%
Doxepine	1,000	100%
Desipramine	500	200%
Imipramine	1,000	100%
Promethazine	1,000	100%
Trimipramine	5,000	20%

PPX

Compound	Concentration (ng/mL)	% Cross-reactivity
Propoxyphene	300	100%
Nor-propoxyphene	300	100%

Interference Study:

The following unrelated compounds were found not to cross-react when tested spiked (100 µg/mL) into drug-free urine, as well as into urine spiked with ± 25% of the cut-off concentration for each individual drug:

Acetaminophen	Erythromycin	Penicillin-G
Acetone	Ethanol	Pheniramine
Acetylsalicylic acid	Furosemide	Phenothiazine
Albumin	Glucose	L-Phenylephrine
Ampicillin	Guaiacol glyceryl ether	B-Phenylethylamin
Ascorbic Acid	Hemoglobin	Phencyclidine
Aspartame	Ibuprofen	Procaine
Aspirin	Ketamine	Propoxyphene
Atropine	Levorphanol	Quinidine
Benzocaine	Lidocaine	Ranitidine
Benzoic acid	Lysergic acid	Riboflavin
Benzoylcegonine	Methadone	Salicylic acid
Bilirubin	Methanol	Secobarbital
Caffeine	Methaqualone	Sodium Chloride
Chlorquine	Morphine	Sulindac
(±) Chlolorpheniramine	(1R,2S)-(-)-n-Methyl-ephedrine	Theophylline
Creatine	(+)-Naproxen	Tyramine

Dexbrompheniramine	Niacinamide	Uric acid
Dextromethorphan	Nicotine	Vitamin (L-Ascorbic Acid)
Dophenhydramine	(+/-)-Norephedrine	4-Dimethylaminoantipyrine
Dopamine	Nortriptyline	d-Amphetamine
(+/-)-Isoproterenol	Nordiazepam	
1R,2S(+)-Ephedrine	Oxalic acid	

Evaluation of Specific Gravity and pH on test results:

To evaluate the effect of pH value on the test results, negative urine samples were adjusted to pH levels 3.0, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0. The samples were then spiked with drug at +/-25% of the cutoff values. Testing was performed on 3 lots/device (dip card, cassette and cup).

To evaluate the effect of specific gravity, samples specific gravities of 1.010, 1.020, and 1.030, were spiked with drug at +/-25% of the cut-off values. Testing was performed on 3 lots/device (dip card, cassette and cup).

The testing results demonstrate that varying pH's and specific gravities do not affect urine testing results around each analyte cut-off.

f. Assay cut-off:

The cut-off characterization study results can be found in the precision section of this summary.

2. Comparison studies:

a. Method comparison with predicate device:

In order to characterize performance of the Advin Multi-Drug Screen Tests compared with Mass Spectrometry testing, forty drug-free urine samples were collected from presumed non-user volunteers and at least 40 drug positive unaltered urine specimens for each drug test were obtained from several reference labs. Each specimen was tested with Advin Multi-Drug Screen Test Cassette, Dip card and Cup by 3 operators at 1 POC site. Results are presented below.

Drug	Candidate Cassette Device Results	Negative	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)
AMP	Positive	0	1	4	45
	Negative	40	3	0	0
Barb	Positive	0	2	7	36
	Negative	40	2	0	0
Bup	Positive	0	2	8	32
	Negative	40	2	0	0
BZO	Positive	0	3	7	34
	Negative	40	1	0	0
COC	Positive	0	1	5	53
	Negative	40	3	0	0
EDDP	Positive	0	3	7	33
	Negative	40	1	0	0
MDMA	Positive	0	2	6	34
	Negative	40	2	0	0
METH	Positive	0	3	4	51
	Negative	40	1	0	0
MOR	Positive	0	3	4	53
	Negative	40	1	0	0
MTD	Positive	0	2	4	37
	Negative	40	2	0	0
OPI	Positive	0	2	7	40
	Negative	40	1	0	0
OXY	Positive	0	3	8	33
	Negative	40	1	0	0
PCP	Positive	0	1	11	33
	Negative	40	3	0	0
PPX	Positive	0	3	7	33
	Negative	40	1	0	0
TCA	Positive	0	2	12	28
	Negative	40	2	0	0
THC	Positive	0	1	11	44
	Negative	40	3	0	0

Analysis of Discordant Results with Advin Multi-Drug Screen Test Cassette

Drug Test/Cutoff (ng/mL)	Advin Multi-Drug Screen Test Cassette Discordant Test Result (Positive or Negative by Visual Read)	GC/MS or LCMS Analysis	
		Drug Concentration (ng/mL)	Drug in Urine
AMP/500	Positive	477	Amphetamine
BZO/300	Positive	244	Oxazepam
BZO/300	Positive	252	Oxazepam
BZO/300	Positive	295	Oxazepam
COC/150	Positive	146	Benzoyllecgonine
EDDP/300	Positive	250	EDDP
EDDP/300	Positive	263	EDDP
EDDP/300	Positive	275	EDDP
BAR/300	Positive	265	Barbital
BAR/300	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
BUP/10	Positive	9	Buprenorphine
OXY/100	Positive	88	Oxycodone
OXY/100	Positive	98	Oxycodone
OXY/100	Positive	99	Oxycodone
OPI/2,000	Positive	1,898	Morphine
OPI/2,000	Positive	1,990	Morphine
MOR/300	Positive	260	Morphine
MOR/300	Positive	263	Morphine
MOR/300	Positive	292	Morphine
MET/500	Positive	394	Methamphetamine
MET/500	Positive	461	Methamphetamine
MET/500	Positive	1809	Methamphetamine Amphetamine
MTD/300	Positive	266	Methadone
MTD/300	Positive	273	Methadone
PPX/300	Positive	242	Norpropoxyphene
PPX/300	Positive	285	Norpropoxyphene
PCP/25	Positive	22.9	Phencyclidine
THC/50	Positive	49	11-nor- Δ^9 -THC-9-COOH
TCA/1,000	Positive	786	Nortriptyline
TCA/1,000	Positive	859	Nortriptyline
MDMA/500	Positive	368	MDMA
MDMA/500	Positive	439	MDMA MDA

Drug	Candidate Dipcard Device Results	Negative	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)
AMP	Positive	0	1	4	45
	Negative	40	3	0	0
Barb	Positive	0	2	7	36
	Negative	40	2	0	0
Bup	Positive	0	2	8	32
	Negative	40	2	0	0
BZO	Positive	0	3	7	34
	Negative	40	1	0	0
COC	Positive	0	1	4	36
	Negative	40	3	0	0
EDDP	Positive	0	3	7	33
	Negative	40	1	0	0
MDMA	Positive	0	2	6	34
	Negative	40	2	0	0
METH	Positive	0	3	4	51
	Negative	40	1	0	0
MOR	Positive	0	3	4	53
	Negative	40	1	0	0
MTD	Positive	0	2	4	37
	Negative	40	2	0	0
OPI	Positive	0	2	7	40
	Negative	40	1	0	0
OXY	Positive	0	3	8	33
	Negative	40	1	0	0
PCP	Positive	0	1	11	33
	Negative	40	3	0	0
PPX	Positive	0	3	7	33
	Negative	40	1	0	0
TCA	Positive	0	2	12	28
	Negative	40	2	0	0
THC	Positive	0	1	11	44
	Negative	40	3	0	0

Analysis of Discordant Result with Advin Multi-Drug Screen Test Dipcard

Assay Cutoff value	Device Pos/Neg	Major metabolite by GC/MS or LC/MS
AMP500	Positive	477 Amphetamine
BZO300	Positive	244 Oxaxepam
BZO300	Positive	252 Oxaxepam
BZO300	Positive	295 Oxaxepam
COC150	Positive	146 Benzoylcegonine
EDDP300	Positive	250 EDDP
EDDP300	Positive	263 EDDP
EDDP300	Positive	275 EDDP
BAR300	Positive	265 Barbitol
BAR300	Positive	286 Barbitol
BUP10	Positive	8 Buprenorphine
BUP10	Positive	9 Buprenorphine
OXY100	Positive	88 Oxycodone
OXY100	Positive	98 Oxycodone
OXY100	Positive	99 Oxycodone
OPI2,000	Positive	1,898 Morphine
OPI2,000	Positive	1,990 Morphine
MOR300	Positive	260 Morphine
MOR300	Positive	263 Morphine
MOR300	Positive	292 Morphine
MET500	Positive	394 Methamphetamine
MET500	Positive	461 Methamphetamine
MET500	Positive	1809 Methamphetamine, Amphetamine
MTD300	Positive	266 Methadone
MTD300	Positive	273 Methadone
PPX300	Positive	242 Norpropoxyphene
PPX300	Positive	285 Norpropoxyphene
PCP25	Positive	22.9 Phencyclidine
THC50	Positive	49 11-nor- Δ^9 -THC-9-COOH
TCA1,000	Positive	786 Nortriptyline
TCA1,000	Positive	859 Nortriptyline
MDMA500	Positive	368 MDMA
MDMA500	Positive	439 MDMA, MDA

Drug	Candidate CupDevice Results	Negative	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)
AMP	Positive	0	1	4	45
	Negative	40	3	0	0
Barb	Positive	0	2	7	36
	Negative	40	2	0	0
Bup	Positive	0	2	8	32
	Negative	40	2	0	0
BZO	Positive	0	3	7	34
	Negative	40	1	0	0
COC	Positive	0	1	5	53
	Negative	40	3	0	0
EDDP	Positive	0	3	7	33
	Negative	40	1	0	0
MDMA	Positive	0	2	6	34
	Negative	40	2	0	0
METH	Positive	0	3	4	51
	Negative	40	1	0	0
MOR	Positive	0	3	4	53
	Negative	40	1	0	0
MTD	Positive	0	2	4	37
	Negative	40	2	0	0
OPI	Positive	0	2	7	40
	Negative	40	1	0	0
OXY	Positive	0	3	8	33
	Negative	40	1	0	0
PCP	Positive	0	1	11	33
	Negative	40	3	0	0
PPX	Positive	0	3	7	33
	Negative	40	1	0	0
TCA	Positive	0	2	12	28
	Negative	40	2	0	0
THC	Positive	0	1	11	44
	Negative	40	3	0	0

Analysis of Discordant Results with Advin Multi-Drug Screen Test Cup

Drug Test/Cutoff (ng/mL)	Advin Multi-Drug Screen Test Cassette Discordant Test Result (Positive or Negative by Visual Read)	GC/MS or LCMS Analysis	
		Drug Concentration (ng/mL)	Drug in Urine
AMP/500	Positive	477	Amphetamine
BZO/300	Positive	244	Oxazepam
BZO/300	Positive	252	Oxazepam
BZO/300	Positive	295	Oxazepam
COC/150	Positive	146	Benzoylcegonine
EDDP/300	Positive	250	EDDP
EDDP/300	Positive	263	EDDP
EDDP/300	Positive	275	EDDP
BAR/300	Positive	265	Barbital
BAR/300	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
BUP/10	Positive	9	Buprenorphine
OXY/100	Positive	88	Oxycodone
OXY/100	Positive	98	Oxycodone
OXY/100	Positive	99	Oxycodone
OPI/2,000	Positive	1,898	Morphine
OPI/2,000	Positive	1,990	Morphine
MOR/300	Positive	260	Morphine
MOR/300	Positive	263	Morphine
MOR/300	Positive	292	Morphine
MET/500	Positive	394	Methamphetamine
MET/500	Positive	461	Methamphetamine
MET/500	Positive	1809	Methamphetamine Amphetamine
MTD/300	Positive	266	Methadone
MTD/300	Positive	273	Methadone
PPX/300	Positive	242	Norpropoxyphene
PPX/300	Positive	285	Norpropoxyphene
PCP/25	Positive	22.9	Phencyclidine
THC/50	Positive	49	11-nor- Δ^9 -THC-9-COOH
TCA/1,000	Positive	786	Nortriptyline
TCA/1,000	Positive	859	Nortriptyline
MDMA/500	Positive	368	MDMA
MDMA/500	Positive	439	MDMA MDA

b. *Matrix comparison:*

Not applicable. The assay is intended for only one sample matrix.

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):*

Consumer Study:

Drug-free urine samples were spiked with following different drugs to different concentrations: +/- 50% cutoff, +/-25% cutoff and 0% cutoff. Each solution was labeled with different code numbers.

One hundred male and female persons age 18 or older participated in the lay person user study for the Advin Multi -Drug Screen Test. Each participant performed 2–5 tests on provided specimens with each of the three formats of Advin Multi-Drug Screen Test (Cassette, Dip Card and Cup) by following the instructions in the product package inserts. The test solutions were blinded and randomized for different test formats. Each level of the drug solutions was randomly tested with 20- 24 replicates. Over 100 test results for a total of 6 drug concentration levels were obtained from the lay users study. Study participants recorded the test results on provided data sheets. Results are shown below.

Cassette

Drug	Result	Drug Concentration				
		Negative	-50%	-25%	+25%	+50%
AMP 500 ng/mL	Negative	44	44	36	7	0
	Positive	0	0	12	36	43
	Total	44	44	48	43	43
	Agreement	100%	100%	75%	83.7%	100%
BAR 300 ng/mL	Negative	24	20	16	4	0
	Positive	0	0	5	16	24
	Total	24	20	21	20	24
	Agreement	100%	100%	76.2%	80%	100%
BUP 10 ng/mL	Negative	24	20	16	6	0
	Positive	0	0	6	18	20
	Total	24	20	22	24	20
	Agreement	100%	100%	72.7%	75%	100%

BZO 300 ng/mL	Negative	21	20	18	4	0
	Positive	0	0	6	16	21
	Total	21	20	24	20	21
	Agreement	100%	100%	75%	80%	100%
COC 150 ng/mL	Negative	20	24	18	4	0
	Positive	0	0	6	17	21
	Total	20	24	24	21	21
	Agreement	100%	100%	75%	80.9%	100%
EDDP 300 ng/mL	Negative	22	24	15	6	0
	Positive	0	0	5	14	22
	Total	22	24	20	20	22
	Agreement	100%	100%	75%	70%	100%
MET 500 ng/mL	Negative	21	21	14	5	0
	Positive	0	0	6	19	20
	Total	21	21	20	24	20
	Agreement	100%	100%	70%	75%	100%
MDMA 500 ng/mL	Negative	20	22	14	6	0
	Positive	0	0	6	18	22
	Total	20	22	20	24	22
	Agreement	100%	100%	70%	75%	100%
MTD 300 ng/mL	Negative	22	22	13	3	0
	Positive	0	0	7	17	24
	Total	22	22	20	20	24
	Agreement	100%	100%	65%	85%	100%
MOR 300 ng/mL	Negative	20	21	16	6	0
	Positive	0	0	5	18	23
	Total	20	21	21	24	23
	Agreement	100%	100%	76%	75%	100%
OPI 2000 ng/mL	Negative	20	22	17	4	0
	Positive	0	0	5	16	24
	Total	20	22	22	20	24
	Agreement	100%	100%	77.2%	80%	100%
OXY 100 ng/mL	Negative	24	24	16	3	0
	Positive	0	0	6	19	20
	Total	24	24	22	22	20
	Agreement	100%	100%	72.7%	86.4%	100%
PCP 25 ng/mL	Negative	24	24	13	3	0
	Positive	0	0	7	18	20
	Total	24	24	20	21	20
	Agreement	100%	100%	65%	95.7%	100%
TCA 1000 ng/mL	Negative	24	20	18	4	0
	Positive	0	0	6	18	20
	Total	24	20	24	22	20
	Agreement	100%	100%	75%	81.8%	100%
THC	Negative	20	21	15	5	0

50 ng/mL	Positive	0	0	6	19	24
	Total	20	21	21	24	24
	Agreement	100%	100%	71.4%	79.2	100%

Dip card

Drug	Result	Drug Concentration				
		Negative	-50%	-25%	+25%	+50%
AMP 500 ng/mL	Negative	41	45	29	8	0
	Positive	0	0	11	36	42
	Total	41	45	40	44	42
	Agreement	100%	100%	72.5%	81.8%	100%
BAR 300 ng/mL	Negative	24	20	17	6	0
	Positive	0	0	5	14	20
	Total	24	20	22	20	20
	Agreement	100%	100%	77.3%	70%	100%
BUP 10 ng/mL	Negative	20	22	17	4	0
	Positive	0	0	4	17	21
	Total	20	22	21	21	21
	Agreement	100%	100%	81%	81%	100%
BZO 300 ng/mL	Negative	23	20	16	4	0
	Positive	0	0	4	16	22
	Total	23	20	20	20	22
	Agreement	100%	100%	80%	80%	100%
COC 150 ng/mL	Negative	20	20	19	4	0
	Positive	0	0	5	18	23
	Total	20	20	24	22	23
	Agreement	100%	100%	79.1%	81.8%	100%
EDDP 300 ng/mL	Negative	20	21	16	6	0
	Positive	0	0	5	16	21
	Total	20	21	21	22	21
	Agreement	100%	100%	76.2%	72.7%	100%
MET 500 ng/mL	Negative	23	22	14	4	0
	Positive	0	0	6	16	20
	Total	23	22	20	20	20
	Agreement	100%	100%	70%	80%	100%
MDMA 500 ng/mL	Negative	22	20	16	6	0
	Positive	0	0	5	14	21
	Total	22	20	21	20	21
	Agreement	100%	100%	76.2%	70%	100%
MTD 300 ng/mL	Negative	20	0	16	5	0
	Positive	0	21	6	16	20
	Total	20	21	22	21	20
	Agreement	100%	100%	72.7%	76.2%	100%
MOR	Negative	20	23	17	4	0

300 ng/mL	Positive	0	0	5	20	20
	Total	20	23	22	24	20
	Agreement	100%	100%	77.3%	83.4%	100%
OPI 2000 ng/mL	Negative	22	21	15	5	0
	Positive	0	0	5	16	20
	Total	22	21	20	21	20
	Agreement	100%	100%	75%	76.2%	100%
OXY 100 ng/mL	Negative	21	20	16	4	0
	Positive	0	0	5	16	21
	Total	21	20	21	20	21
	Agreement	100%	100%	76.2%	80%	100%
PCP 25 ng/mL	Negative	24	20	15	4	0
	Positive	0	0	5	18	20
	Total	24	20	20	22	20
	Agreement	100%	100%	75%	81.8%	100%
TCA 1000 ng/mL	Negative	20	21	16	4	0
	Positive	0	0	5	17	22
	Total	20	21	21	21	22
	Agreement	100%	100%	76.2%	80.9%	100%
THC 50 ng/mL	Negative	20	22	17	4	0
	Positive	0	0	6	16	24
	Total	20	22	23	20	24
	Agreement	100%	100%	73.9%	80%	100%

Cup

Drug	Result	Drug Concentration				
		Negative	-50%	-25%	+25%	+50%
AMP 500 ng/mL	Negative	90	82	61	22	0
	Positive	0	0	23	68	86
	Total	90	82	84	90	86
	Agreement	100%	100%	72.8%	75.5%	100%
BAR 300 ng/mL	Negative	152	21	15	6	0
	Positive	0	0	5	15	21
	Total	152	21	20	21	21
	Agreement	100%	100%	75%	71.4%	100%
BUP 10 ng/mL	Negative	148	21	18	6	0
	Positive	0	0	4	18	20
	Total	148	21	22	24	20
	Agreement	100%	100%	81.8%	75%	100%
BZO 300 ng/mL	Negative	154	21	15	4	0
	Positive	0	0	6	17	20
	Total	154	21	21	21	20
	Agreement	100%	100%	71.4%	80.9%	100%
COC	Negative	152	21	15	5	0

150 ng/mL	Positive	0	0	6	15	23
	Total	152	21	21	20	23
	Agreement	100%	100%	71.4%	75%	100%
EDDP 300 ng/mL	Negative	150	24	14	5	0
	Positive	0	0	6	16	22
	Total	150	24	20	21	22
	Agreement	100%	100%	70%	76.2%	100%
MET 500 ng/mL	Negative	154	20	15	5	0
	Positive	0	0	6	16	21
	Total	154	20	21	21	21
	Agreement	100%	100%	71.4%	76.2%	100%
MDMA 500 ng/mL	Negative	148	23	15	6	0
	Positive	0	0	5	15	22
	Total	148	23	20	21	22
	Agreement	100%	100%	75%	71.4%	100%
MTD 300 ng/mL	Negative	150	22	16	5	0
	Positive	0	0	5	15	24
	Total	150	22	21	20	24
	Agreement	100%	100%	76.2%	75%	100%
MOR 300 ng/mL	Negative	84	23	14	5	0
	Positive	0	0	6	16	21
	Total	84	23	20	21	21
	Agreement	100%	100%	70%	76.2%	100%
OPI 2000 ng/mL	Negative	84	22	18	4	0
	Positive	0	0	5	16	21
	Total	84	22	23	20	21
	Agreement	100%	100%	78.3%	80%	100%
OXY 100 ng/mL	Negative	151	21	15	5	0
	Positive	0	0	7	18	20
	Total	151	21	22	23	20
	Agreement	100%	100%	68.2%	78.3%	100%
PCP 25 ng/mL	Negative	152	21	15	4	0
	Positive	0	0	6	16	21
	Total	152	21	21	20	21
	Agreement	100%	100%	71.4%	80%	100%
TCA 1000 ng/mL	Negative	148	20	19	6	0
	Positive	0	0	5	16	21
	Total	148	20	24	22	21
	Agreement	100%	100%	79.2%	72.7%	100%
THC 50 ng/mL	Negative	152	20	17	5	0
	Positive	0	0	6	16	21
	Total	152	20	23	21	21
	Agreement	100%	100%	73.9%	76.2%	100%

A post-test survey of volunteers showed that 100% thought that the test was easy to use and easy to read. A Flesh-Kincaid reading analysis resulted in a reading grade level of 7.8.

Read Time

Drug standards at the concentration of 0, -50% and +50% cutoff level were tested in triplicates with the Advin Multi-Drug Screen Test Cassettes, Dip Card and Cup formats following the procedures described in the proposed package inserts. The result was read visually as positive or negative at 5, 10, 30, 60 and 120 minutes. Results showed that the test results are stable for up to 120 minutes.

Adulteration Testing

To demonstrate that the technicians at POC sites are able to follow the product package insert to perform Advin urine adulteration test when the urine adulteration strips are included in Advin Multi-drug Screen Test Cassette, Dip Card and Cup, drug standards were spiked into drug-free urine samples at 0% cutoff, -50% cutoff, - 25% cutoff, at cutoff, +25% cutoff and +50% cutoff, and bleach, nitrate, sodium chloride, and glutaraldehyde were spiked into samples as adulterants. Each adulterated sample was tested in triplicates on each of the Advin Urine Adulteration test formats, by three office technicians at three POC sites. Results showed that the Advin Urine Adulteration tests were able to detect adulteration under these specific conditions 100% of the time.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

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

O. Conclusion:

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