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

A. 510(k) Number:

k182123

B. Purpose for Submission:

Modification of a previously cleared device (k122809) to add Amphetamine (1000 ng/mL cutoff), Methamphetamine (1000 ng/mL cutoff), Cocaine (300 ng/mL cutoff), and 6-Acetylmorphine devices (10 ng/mL cutoff), and to change the formulation of the previously cleared Morphine device.

C. Measurands:

Amphetamine, Methamphetamine, Cocaine, Morphine, and 6-Acetylmorphine

D. Type of Test:

Qualitative, lateral flow immunoassay

E. Applicant:

Advin Biotech, Inc.

F. Proprietary and Established Names:

ATTEST Drug Screen Cup
ATTEST Drug Screen Dip Card

G. Regulatory Information:

Regulation names	Product Code	Class	Regulation	Panel
Opiate Test System	DJG	II	862.3650	Toxicology (91)
Amphetamine Test system	DKZ	II	862.3100	Toxicology (91)
Cocaine and metabolites Test System	DIO	II	862.3250	Toxicology (91)
Methamphetamine Test System	DJC	II	862.3610	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use

2. Indication(s) for use:

   The ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card are rapid lateral flow immunoassays for the qualitative detection of 6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital and THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Calibrator	Cutoff (ng/mL)
6-Acetylmorphine	6-monoacetylmorphine	10
Amphetamine	d-Amphetamine	500
Amphetamine	d-Amphetamine	1,000
Barbiturates	Secobarbital/Pentobarbital	300
Benzodiazepines	Oxazepam	300
Buprenorphine	Buprenorphine	10
EDDP	2-ethylidene-1,5-dimethyl-3-3-diphenylpyrrolidine	300
Cocaine	Benzoylecgonine	150
Cocaine	Benzoylecgonine	300
Ecstasy	d,l-Methylenedioxymethamphetamine	500
Methamphetamine	d-Methamphetamine	500
Methamphetamine	d-Methamphetamine	1,000
Marijuana	11-nor-Δ^9-THC-9-COOH	50
Methadone	d/l-Methadone	300
Opiates	Morphine	300
Opiates	Morphine	2,000
Oxycodone	Oxycodone	100
Phencyclidine	Phencyclidine	25
Propoxyphene	Propoxyphene	300
Tricyclic Antidepressants	Nortriptyline	1,000

The single or multi-test panels can consist of the above listed analytes in any combination, up to a maximum of 16 analytes, with and without on-board

adulteration/specimen validity tests (SVT) in the dip card format and in the cup format. The drug screen tests are intended for prescription use only.

The tests provide only a preliminary result. A more specific alternative chemical method should be used in order to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography / Mass Spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

3. Special conditions for use statement(s):

   This assay is intended for prescription use

4. Special instrument requirements:

   Not applicable.

I. Device Description:

The ATTEST Drug Screen Cup and ATTEST Drug Screen Dip Card devices are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Methamphetamine, Barbiturates, Benzodiazepine, Cannabinoids, Cocaine, Methadone, Tricyclic antidepressants, Buprenorphine, EDDP, MDMA, Morphine, Oxycodone, Phencyclidine, Propoxyphene, and 6-Acetylmorphine. The ATTEST Drug Screen Cup device consists of a cup device and a package insert. The ATTEST Drug Screen Dip Card device consists of a Dip Card device, a package insert and a urine cup for sample collection.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Advin Multi-Drug Screen Test Cup,
   Advin Multi-Drug Screen Test Dipcard

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

   k122809

3. Comparison with predicate:

Predicate Similarities and Differences Table for All Assays

Similarities		
Item	Candidate Devic	Predicate Device (k122809)
Intended Use	Same	Qualitative detection of drugs of abuse and/or their metabolites in urine
Test Principle	Same	Lateral flow immunochromatographic assay based on competitive binding
Matrix	Same	Urine
Analyte cutoffs (ng/mL)	Same except for the following analytes: 6-AM - 10 Amphetamine - 1,000 Cocaine - 300 Methamphetamine - 1,000 Opiates - 300	Amphetamine - 500 Barbiturates - 300 Benzodiazepine - 300 Buprenorphine - 10 Cocaine - 150 EDDP - 300 Ecstasy - 500 Methamphetamine - 500 Methadone - 300 Morphine - 300 Opiates - 2,000 Oxycodone - 100 Phencyclidine - 25 Propoxyphene - 300 Tricyclics - 1,000 Marijuana - 50
Differences		
Formats	Cup and Dip Card only	Cup, Dip Card, Cassette

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

None referenced

L. Test Principle:

Each device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of the antibody coated particles on the drug specific test strips. The goat-anti-rabbit IgG antibody-coated particles will then be captured by immobilized drug-specific conjugate. If the level of drug in the urine specimen is below the cutoff concentration, the T line appears as a visible burgundy line. If the level of drug in the urine specimen is above the cutoff, no T line develops.

The control line (C line) serves as an internal quality control. The control line should always

appear as a burgundy-colored band regardless of the presence of the drug, if enough sample volume has been added to the test and if the sample has correctly migrated up the test strip. Testing is based on the principle of a competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample competing for the limited antibody binding sites.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision study of the ATTEST Drug Screen Cup and Dip card were evaluated for Amphetamine (1000 ng/mL cutoff, AMP 1000), Methamphetamine (1000 ng/mL cutoff, MET 1000), Cocaine (300 ng/mL cutoff, COC 300), Opiates (300 ng/mL cutoff, OPI 300) and 6-Acetylmorphine devices (10 ng/mL cutoff, 6-AM 10) at three external testing sites. Samples tested were drug free urine spiked with certified reference standards to the target concentrations. The test solutions contain the following drug concentrations: negative, +/-75% cutoff, +/-50% cutoff, +/-25% cutoff, and +100% cutoff. All test solutions were confirmed by a chemically specific quantitative method to verify the drug concentrations.

Three operators performed the study using three lots of ATTEST Cup Drug Screen and three lots of ATTEST Card Drug Screen. Each sample was tested in 20 replicates for each device format at each of three sites. A total of 180 specimens for each device format were tested over 10 non-consecutive days. The results are shown in the tables below. Performance data for Amphetamine (500 ng/mL cutoff), Barbiturates, Benzodiazepines, Buprenorphine, EDDP, Cocaine (150 ng/mL cutoff), Ecstasy, Methamphetamine (500 ng/mL cutoff), Marijuana, Methadone, Opiates (2000 ng/mL cutoff), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants was provided in k122809.

Precision Study Result of ATTEST Cup:

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
6-AM 10	Neg	60	60	60	58	32	0	0	0	0
	Pos	0	0	0	2	28	60	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	97%	-------	100%	100%	100%	100%
AMP 1000	Neg	60	60	60	58	5	1	0	0	0
	Pos	0	0	0	2	55	59	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	97%	------	98%	100%	100%	100%

COC 300	Neg	60	60	60	59	22	1	0	0	0
	Pos	0	0	0	1	38	59	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	98%	------	98%	100%	100%	100%
MET 1000	Neg	60	60	60	58	26	3	0	0	0
	Pos	0	0	0	2	34	57	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	97%	------	95%	100%	100%	100%
OPI 300	Neg	60	60	60	56	10	4	0	0	0
	Pos	0	0	0	4	50	56	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	93%	------	93%	100%	100%	100%

Precision Study Result of ATTEST Dip Card:

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
6-AM 10	Neg	60	60	60	59	23	1	0	0	0
	Pos	0	0	0	1	37	59	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	98%	-------	98%	100%	100%	100%
AMP 1000	Neg	60	60	60	60	18	2	0	0	0
	Pos	0	0	0	0	42	58	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	100%	------	97%	100%	100%	100%
COC 300	Neg	60	60	60	57	18	1	0	0	0
	Pos	0	0	0	3	42	59	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	95%	------	98%	100%	100%	100%
MET 1000	Neg	60	60	60	59	31	2	0	0	0
	Pos	0	0	0	1	29	58	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	98%	------	97%	100%	100%	100%
OPI 300	Neg	60	60	60	59	21	1	0	0	0
	Pos	0	0	0	1	39	59	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100%	100%	100%	98%	------	98%	100%	100%	100%

b. Linearity/assay reportable range:

Not applicable.

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

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. There are no external controls supplied with the device.

Device stability has been evaluated through accelerated and real-time studies. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims that the devices are stable for 28 months.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Analytical specificity for both the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card was determined through the testing of contrived solutions made by spiking certified standards of chemically-related or structurally-similar compounds into drug free urine. The relative cross-reactivity represents the minimum concentration necessary to yield a result similar to the cutoff level of the respective assay. Identical results, provided in the table below, were obtained with the two devices. Performance data for Amphetamine (500 ng/mL cutoff), Barbiturates, Benzodiazepines, Buprenorphine, EDDP, Cocaine (150 ng/mL cutoff), Ecstasy, Methamphetamine (500 ng/mL cutoff), Marijuana, Methadone, Opiates (2000 ng/mL cutoff), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants was provided in k122809.

Assay/Cutoff	**Compound**	**Concentration (ng/mL)**	**Relative cross-reactivity (%)**
6-AM 10	6-acetylmorphine	10	100
	Diacetylmorphine (heroin)	300	3.3
	Morphine	>100,000	<0.1
	Codeine	>100,000	<0.1
	Oxycodone	>100,000	<0.1
	Oxymorphone	>100,000	<0.1
AMP 1000	d-Amphetamine	1,000	100
	l-Amphetamine	100,000	1
	MDA	15,000	6.7
	Phentermine	100,000	1.0
COC 300	Benzoylecgonine	300	100
	Cocaethylene	100,000	0.3
	Cocaine	10,000	3

Assay/Cutoff	Compound	Concentration (ng/mL)	Relative cross-reactivity (%)
	Ecgonine	100,000	0.3
MET 1000	d-Methamphetamine	1,000	100
	l-Methamphetamine	30,000	3.3
	d-Amphetamine	100,000	1
	l-Amphetamine	100,000	1
	1R, 2S(1)-Ephedrine	>100,000	<0.5
	MDEA	60,000	1.7
	MDMA	8,000	12.5
	Mephentermine	100,000	1
OPI 300	Morphine	300	100
	6-Acetylmorphine (6-AM)	400	75
	Codeine	100	300
	Codeine-6-β-glucuronide	150	200
	Ethylmorphine	150	200
	Diacetylmorphine (heroin)	900	33.3
	Hydrocodone	500	60
	Hydromorphone	600	50
	Levorphanol	10,000	3
	Morphine-3-glucuronide	450	66.7
	Norcodeine	30,000	1
	Oxycodone	70,000	<0.5
	Thebaine	20,000	1.5

The potential interference from compounds chemically dissimilar to target drugs, and known endogenous agents was also determined for both the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card. Testing of compounds and endogenous agents was performed by spiking the substances noted in the table below into pooled urine containing target drugs at near-cutoff concentrations. Identical results, provided in the table below, were obtained with the two devices. Unless otherwise indicated, substances were tested for potential interference at a concentration of 100 µg/mL. Performance data for Amphetamine (500 ng/mL cutoff), Barbiturates, Benzodiazepines, Buprenorphine, EDDP, Cocaine (150 ng/mL cutoff), Ecstasy, Methamphetamine (500 ng/mL cutoff), Marijuana, Methadone, Opiates (2000 ng/mL cutoff), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants was provided in k122809.

The following substances demonstrated no interference to the assays encompassed in this submission.

Acetaminophen	Acetone	Acetylsalicylic acid
Albumin	Ampicillin	Ascorbic acid
Aspartame	Atropine	Benzocaine
Bilirubin	Caffeine	Chloroquine
Chlorpheniramine	Creatine	Dexbrompheniramine
Dextromethorphan	Dimethylaminoantipyrine	Diphenhydramine
Dimenhydrinate	Dopamine	Isoproterenol
Ephedrine	Erythromycin	Ethanol
Furosemide	Gabapentin	Glucose

Guaiacol glyceryl ether	Hemoglobin	Ibuprofen
Isoproterenol	Ketamine	Lidocaine
Methylephedrine	Naproxen	Niacinamide
Nicotine	Norephedrine	Oxalic acid
Pantoprazole	Penicillin-G	Pheniramine
Phenothiazine	l-Phenylephrine	B-Phenylethylamine
Pregablin	Procaine	Quinidine
Ranitidine	Riboflavin	Sertraline
Sodium chloride	Sulindac	Theophylline
Tyramine		

Interference from pH and specific gravity variation was also evaluated for both the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card using pooled urine specimens containing target drugs at near-cutoff concentrations. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.003 to 1.030 do not affect the results of the assays for either of the devices. Performance data for Amphetamine (500 ng/mL cutoff), Barbiturates, Benzodiazepines, Buprenorphine, EDDP, Cocaine (150 ng/mL cutoff), Ecstasy, Methamphetamine (500 ng/mL cutoff), Marijuana, Methadone, Opiates (2000 ng/mL cutoff), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants was provided in k122809.

f. Assay cut-off:

For characterization of how the device performs analytically around the claimed cutoff concentration, please refer to section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted for the ATTEST Drug Screen Cup and ATTEST Drug Screen Dip card, using clinical urine specimens quantitated for the target drugs of abuse by chemically specific quantitative methods (e.g. LC-MS). Identical results, provided in the table below, were obtained with the two devices. Performance data for Amphetamine (500 ng/mL cutoff), Barbiturates, Benzodiazepines, Buprenorphine, EDDP, Cocaine (150 ng/mL cutoff), Ecstasy, Methamphetamine (500 ng/mL cutoff), Marijuana, Methadone, Opiates (2000 ng/mL cutoff), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants was provided in k122809.

Device	Device Result	Concentration determined by chemically specific quantitative method (e.g. LC/MS)			
		≤50% cutoff concentration	Near Cutoff Negative (-50% to the cutoff concentration)	Near Cutoff Positive (cutoff to 150% of the cutoff)	High Positive (≥150% of the cutoff)
6-AM/10	Negative	40	5	0	0
	Positive	0	0	5	35
AMP/1000	Negative	40	6	0	0
	Positive	0	0	6	40
COC/300	Negative	40	5	0	0
	Positive	0	0	5	35
MET/1000	Negative	40	6	0	0
	Positive	0	0	5	40
OPI/300	Negative	40	3	0	0
	Positive	0	1	4	46

Summary of Discordant Results:

Drug / Cutoff (ng/ml)	ATTEST Cup Result	GC/MS result	
		Drug Concentration (ng/ml)	Analyte
OPI/300	Positive	289	Morphine

b. Matrix comparison:

Not applicable.

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):

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 Parts 801 and 809, as applicable.

O. Conclusion:

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