

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

A. 510(k) Number: k131645

B. Purpose for Submission:

Modification of previously cleared devices; addition of new analytes.

C. Measurand:

Amphetamine, Barbituates, Benzodiazepine, Cocaine, Methamphetamine, Methadone, Phencyclidine, Tricyclic antidepressants, Cannabinoid, 3,4-Methylene-dioxymethamphetamine (MDMA), Morphine, Oxycodone.

D. Type of Test:

Qualitative lateral flow chromatographic immunoassay.

E. Applicant:

Alfa Scientific Designs, Inc.

F. Proprietary and Established Names:

Instant-View Multi-Drug of Abuse Urine Test Cup

Instant-View Multi-Drug of Abuse Urine Test Panel

G. Regulatory Information:

Product Code	Regulation name	Regulation section	Panel
DKZ	Amphetamine test system	862.3100	Toxicology (91)
JXM	Benzodiazepine test system	862.3170	
DIO	Cocaine and cocaine metabolite test system.	862.3250	
LDJ	Cannabinoid test system	862.3870	
DJC	Methamphetamine test system	862.3610	
LCM	Phencyclidine test system	Unclassified	
DIS	Barbiturate test system	862.3150	
DJG	Opiate test system	862.3650	
DJR	Methadone test system	862.3620	
LFG	Tricyclic antidepressant drugs test system	862.3910	

H. Intended Use:

1. Intended use(s):
Refer to Indications for Use
2. Indication(s) for use:

Instant-View Multi-Drug of Abuse Urine Test Cup:

The Instant-View Multi-Drug of Abuse Urine Test Cup is a rapid, qualitative immunoassay for the detection of one or more of the following drugs in human urine. This device is for over the counter use and may detect any combination of the drugs or drug metabolites at or above the specified cut-off level listed below.

<u>Abbreviation</u>	<u>Test</u>	<u>Cutoff</u>
<u>AMP</u>	Amphetamine	1000 ng/mL
<u>BAR</u>	Barbiturates	200 ng/mL
<u>BZD</u>	Benzodiazepine	300 ng/mL
<u>COC</u>	Cocaine	300 ng/mL
<u>MDMA</u>	MDMA or Ecstasy	500 ng/mL
<u>MET</u>	Methamphetamine	1000 ng/mL
<u>MTD</u>	Methadone	300 ng/mL
<u>MOR</u>	Morphine/Opiates	2000 ng/mL
<u>OXY</u>	Oxycodone	100 ng/mL
<u>PCP</u>	Phencyclidine	25 ng/mL
<u>TCA</u>	Tricyclic antidepressants	1000 ng/mL
<u>THC</u>	Marijuana	50 ng/mL

The drug tests will provide a preliminary result only. A more specific, alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and High-Performance Liquid Chromatography (HPLC), or the like are the preferred confirmation methods for most drugs in urine. Clinical consideration and professional judgment should be applied to any drug test result, particularly when evaluating preliminary positive results.

Instant-View Multi-Drug of Abuse Urine Test Panel:

The Instant-View Multi-Drug of Abuse Urine Test Panel is a rapid, qualitative immunoassay for the detection of one or more of the following drugs in human urine. This device is for over the counter use and may detect any combination of the drugs or drug metabolites at or above the specified cut-off level listed below.

<u>Abbreviation</u>	<u>Test</u>	<u>Cutoff</u>
<u>AMP</u>	Amphetamine	1000 ng/mL
<u>BAR</u>	Barbiturates	200 ng/mL
<u>BZD</u>	Benzodiazepine	300 ng/mL
<u>COC</u>	Cocaine	300 ng/mL
<u>MDMA</u>	MDMA or Ecstasy	500 ng/mL

<u>MET</u>	Methamphetamine	1000 ng/mL
<u>MTD</u>	Methadone	300 ng/mL
<u>MOR</u>	Morphine/Opiates	300 ng/mL
<u>OXY</u>	Oxycodone	100 ng/mL
<u>PCP</u>	Phencyclidine	25 ng/mL
<u>TCA</u>	Tricyclic antidepressants	1000 ng/mL
<u>THC</u>	Marijuana	50 ng/mL

The drug tests will provide a preliminary result only. A more specific, alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and High-Performance Liquid Chromatography (HPLC), or the like are the preferred confirmation methods for most drugs in urine. Clinical consideration and professional judgment should be applied to any drug test result, particularly when evaluating preliminary positive results.

3. Special conditions for use statement(s):

For Over the Counter Use.

4. Special instrument requirements:

Not applicable; this is a visually read, single use device

I. Device Description:

The Instant-View® Multi-Drug of Abuse Urine Test Cup and the Instant-View® Multi-Drug of Abuse Urine Test Panel are one-step lateral flow chromatographic immunoassays. Each device consists of any combination of one to twelve individual test strip(s) for the analyte(s) being tested. Each test strip in the device consists of 1) a conjugate pad containing colloidal gold coupled with the anti-drug antibodies and 2) nitrocellulose membrane containing a test line (T line) coated with the conjugated drug antigen and a control line (C line). The C line serves as an internal quality control of the system and appears as a burgundy-colored band during the test regardless of the presence of the drug.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Instant -View Multi-Drug of Abuse Urine Test

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

k063545

3. Comparison with predicate:

Similarities		
Item	Predicate Device k063545	Candidate Devices k131645
Intended Use	A rapid qualitative immunoassay for the detection of potential abuse of one or more drugs.	Same
Test Principle	Testing is based on the principle of 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.	Same
Test Strips	Contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test regions and a pad containing colored antibody-colloidal gold conjugate.	Same
Specimen	Urine	Same
Drug(s) detected per test strip	Each test strip detects 1 analyte	Same
Test formats	Cup and panel cassette	Same
Shelf life	24 months	Same
Storage conditions	2 °C to 30 °C	Same

Difference		
Item	Predicate Device	Candidate Devices
The number of analytes in each device	11 analytes	The modified devices have up to 12 analytes including the addition of morphine/opiates 300 (Panel) and oxycodone 100 (Panel and Cup).

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

Draft Guidance for Industry and FDA Staff: Premarket submission and drug labeling recommendations for drugs of abuse screening tests.

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):

Eleven analytes of the candidate devices were previously cleared for OTC use under k063545. The additional analytes of the candidate devices: morphine/opiates 300 and oxycodone 100, were cleared separately for OTC use under k100051. The candidate devices contain test strips identical to k063545 and k100051. Specimen matrix, test formats, and cut-off concentrations and analytes are also identical.

1. Analytical performance:

a. Precision/Reproducibility:

See k063545 and k100051

b. Linearity/assay reportable range:

Not applicable. The assays produce qualitative results only.

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

See k063545 and k100051

d. Detection limit:

See k063545 and k100051

e. Analytical specificity:

For cross-reactivity information see k063545 and k100051.

Interference studies were conducted to evaluate the potential of interference between drug analytes contained in the panel and cup formats. These studies were conducted by three operators using three lots of tests (panel and cup). Expected results were obtained

for all drugs (no interference observed).

Exogenous interference was also evaluated. The common compounds listed in this table were found not to interfere with test results at a test concentration of 100µg/mL. The study results for both formats (cup and panel) are the same.

Compounds
Acetaminophen
Acetylsalicylic acid
Amikacin
Ampicillin
Arterenol
Aspirin
Atropine
Benzoic acid
Caffeine
(+)-Chlorpheniramine
Cortisone
Ethanol
Lidocaine
Methanol
Oxalic acid
Penicillin-G
Phenylpropanolamine
Ranitidine
Salicylic acid
Thioridazine
Trifluoperazine
Albumin
Bilirubin
Creatine
Glucose
Hemoglobin
myoglobin
Uric acid
Vitamin C (l-Ascorbic acid)

pH and specific gravity conditions:

The effects of variable ranges of pH and specific gravity conditions were evaluated, including a pH range of 3 to 9 and a specific gravity range of 0.900 to 1.050 g/mL. It was observed that pH ranges from pH 5 to pH 9 and specific gravity ranges from 1.002 – 1.035 g/mL did not affect the expected testing results (cup or panel).

f. Assay cut-off:

See k063545 and k100051

2. Comparison studies:

a. *Method comparison with predicate device:*

See k063545 and k100051

b. *Matrix comparison:*

See k063545 and k100051

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):*

Lay-user studies were conducted to demonstrate that a full panel cassette or cup of the candidate device (up to 12 test strips) can be interpreted by lay users, correctly. A total of 20 lay-users participated in the panel and cassette studies.

The results are as follows:

Summary of the Results - Panel

Drug	Cutoff Concentration % (ng/ml)	Number of studies	Correctly interpreted	Incorrectly interpreted	% of agreement
AMP	50 (500)	20	20	0	100%
	150 (1500)	20	20	0	100%
	300 (3000)	20	20	0	100%
	0	140	140	0	100%
					average = 100%
BAR	50 (100)	20	20	0	100%
	150 (300)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
BZD	50 (150)	20	20	0	100%
	150 (450)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
COC	50 (150)	20	20	0	100%
	150 (450)	20	20	0	100%
	0	160	160	0	100%
					average = 100%

MET	50 (500)	20	20	0	100%
	150 (1500)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
MTD	50 (150)	20	20	0	100%
	150 (450)	20	20	0	100%
	300 (900)	20	20	0	100%
	0	140	140	0	100%
					average = 100%
PCP	50 (12.5)	20	20	0	100%
	150 (37.5)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
TCA	50 (500)	20	20	0	100%
	150 (1500)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
THC	50 (25)	20	20	0	100%
	150 (75)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
MDMA	50 (250)	20	20	0	100%
	150 (750)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
MOR 300	50 (300)	10	10	0	100%
	75 (225)	10	9	1	90%
	100 (375)	10	9	1	90%
	125 (150)	10	10	0	100%
	150 (450)	10	10	0	100%
	0	40	40	0	100%
					average = 97%
OXY	50 (50)	10	10	0	100%
	75 (75)	10	10	0	100%
	100 (100)	10	8	2	80%
	125 (125)	10	10	0	100%
	150 (150)	10	10	0	100%
	300 (300)	10	10	0	100%
	0	40	40	0	100%
					average = 97%

Summary of the Results – Cup

Drug	Cutoff Concentration % (ng/ml)	Number of studies	Correctly interpreted	Incorrectly interpreted	% of agreement
AMP	50 (500)	20	20	0	100%
	150 (1500)	20	20	0	100%
	300 (3000)	20	20	0	100%
	0	140	140	0	100%
					average = 100%
BAR	50 (100)	20	20	0	100%
	150 (300)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
BZD	50 (150)	20	20	0	100%
	150 (450)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
COC	50 (150)	20	20	0	100%
	150 (450)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
MET	50 (500)	20	20	0	100%
	150 (1500)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
MTD	50 (150)	20	20	0	100%
	150 (450)	20	20	0	100%
	300 (900)	20	20	0	100%
	0	140	140	0	100%
					average = 100%
PCP	50 (12.5)	20	20	0	100%
	150 (37.5)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
TCA	50 (500)	20	20	0	100%
	150 (1500)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
THC	50 (25)	20	20	0	100%
	150 (75)	20	20	0	100%
	0	160	160	0	100%

					average = 100%
MDMA	50 (250)	20	20	0	100%
	150 (750)	20	20	0	100%
	0	160	160	0	100%
					average = 100%
MOR 2000	50 (1000)	10	10	0	100%
	150 (3000)	10	10	0	100%
	0	80	80	0	100%
					average = 100%
OXY	50 (50)	10	10	0	100%
	75 (75)	10	9	1	90%
	100 (100)	10	10	0	100%
	125 (125)	10	10	0	100%
	150 (150)	10	10	0	100%
	300 (300)	10	10	0	100%
	0	40	40	0	100%
					average = 98%

Participants recruited had educational levels from elementary school to college or higher and varied occupations including student, restaurant worker, teacher, stay at home mom, engineer, cashier, etc. All participants completed questionnaires after they completed the testing. The majority of the participants stated that the devices were very easy to operate and they had no difficulties in interpreting the results.

Readability of the labeling was also assessed. The readability score is 7.0 for the cup test and 7.2 for the panel test.

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.