

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

**A. 510(k) Number:**

k152122

**B. Purpose for Submission:**

Over the counter clearance of a device previously cleared for prescription use only.

**C. Measurand:**

Amphetamine, Barbiturates, Buprenorphine, Benzodiazepine, Cocaine, Methamphetamine, Methadone, Phencyclidine, Tricyclic antidepressants, Cannabinoid, 3,4-Methylenedioxymethamphetamine (MDMA), Morphine, Oxycodone.

**D. Type of Test:**

Qualitative

**E. Applicant:**

ALFA Scientific Designs, Inc.

**F. Proprietary and Established Names:**

Instant-View Multi-Drug Urine Test Cup (Home Use)  
Instant-View Multi-Drug Urine Test Panel (Home Use)

**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	8862.3150	
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:

The Instant-View® Multi-Drug Urine Test Cup (Home Use) and Instant-View® Multi-Drug Urine Test Panel (Home Use) are rapid, qualitative immunoassays for the detection in human urine of one or more of the drugs at the cutoff concentrations listed below. These devices will detect up to 13 of the drugs below in any combination. The tests are not intended to distinguish prescription use or abuse of any drugs.

Abbreviation	Test	Calibrator	Cut-off (ng/mL)
AMP	Amphetamine	d-Amphetamine	1000
BAR	Barbiturates	Secobarbital	200
BUP	Buprenorphine	Buprenorphine	10
BZD	Benzodiazepine	Oxazepam	300
COC	Cocaine	Benzoyllecgonine	300
MDMA	MDMA or Ecstasy	Methylenedioxy-methamphetamine	500
MET	Methamphetamine	d-Methamphetamine	1000
MTD	Methadone	Methadone	300
MOR	Morphine/Opiate	Morphine	2000
OXY	Oxycodone	Oxycodone	300
PCP	Phencyclidine	Phencyclidine	25
TCA	Tricyclic Antidepressants	Nortriptyline	1000
THC	Marijuana	11-nor-.69-THC-9-COOH	50

These devices provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

This test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Tests for prescription drugs will yield preliminary positive results when these drugs are

ingested at or above therapeutic doses. There are no uniformly recognized drug levels for prescription drugs in urine. This multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level.

3. Special conditions for use statement(s):

For Over the Counter Use.

4. Special instrument requirements:

Not applicable.

**I. Device Description:**

The Instant View Multi-Drug Urine Test Devices/Cup and the Instant View Multi-Drug Urine Test Devices/Panel Cassettes are one-step lateral flow chromatographic immunoassays. Each device consists of any combination of one to thirteen individual test strips(s) for the analytes(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 Devices/Cup

Instant-View Multi-Drug of Abuse Urine Test Devices/Cassettes

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

k063545

3. Comparison with predicate:

<b>Similarities</b>		
Item	Candidate Device	Predicate Device k063545
Intended Use	Qualitative detection of potential abuse of one or more drugs	Same
Test Principle	Chromatographic	Same

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device</b>	<b>Predicate Device k063545</b>
	immunoassay	
Test Strips	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).	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

<b>Differences</b>		
<b>Item</b>	<b>Candidate Device</b>	<b>Predicate Device k063545</b>
Number of analytes	13	14
Intended Use population	OTC use	Prescription use

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

Not applicable

**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):

This multi-drug test was cleared for prescription use only in k063545. Twelve analytes of the candidate devices were previously cleared for OTC use in k131645. The candidate devices contain test strips identical to k063545 and k131645. Specimen matrix, test formats, and cut-off concentrations and analytes tested are also identical.

Lay user testing for buprenorphine, the only analyte not previously cleared for OTC use, is described in section 3.c. below.

### 1. Analytical performance:

#### a. *Precision/Reproducibility:*

See k063545

#### b. *Linearity/assay reportable range:*

Not applicable

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

See k063545

#### d. *Detection limit:*

See k063545

#### e. *Analytical specificity:*

For exogenous interference, see k063545.

For cross-reactivity information for Amphetamine, Cocaine, Methamphetamine and Oxycodone, see k063545. For cross reactivity information for Buprenorphine, see k060527..

For interference studies to evaluate the potential of interference between drug analytes with the exception of Buprenorphine, see k131645.

#### f. *Assay cut-off:*

See k063545

2. Comparison studies:

a. *Method comparison with predicate device:*

See k063545

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):*

A lay user study was performed at three intended user sites with 400 lay persons testing cup and panel devices. A total of 210 females and 190 males tested the devices. They had diverse educational and professional backgrounds and ranged in age from 18 to >60 years. The participants had no previous experience with an over the counter (OTC) drug test. Urine samples were prepared at the following concentrations: negative,  $\pm 50\%$ ,  $\pm 25\%$  of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package inserts for the test cup and the test panel and performed the test independently without additional help.

The lay user study results are summarized in the tables below:

**Summary of Results for the Cup Format**

<b>Drug</b>	<b>Cutoff Concentration% (ng/ml)</b>	<b>Number of studies</b>	<b>Correctly interpreted</b>	<b>Incorrectly interpreted</b>	<b>% agreement</b>
AMP	0% (0)	350	350	0	100%
	75% (750)	10	8	2	80%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
BAR	0% (0)	350	350	0	100%
	75% (150)	10	9	1	90%
	125% (250)	10	9	1	90%
	150% (300)	30	30	0	100%

<b>Drug</b>	<b>Cutoff Concentration% (ng/ml)</b>	<b>Number of studies</b>	<b>Correctly interpreted</b>	<b>Incorrectly interpreted</b>	<b>% agreement</b>
BUP	0% (0)	20	20	0	100%
	50% (5)	60	60	0	100%
	75% (7.5)	60	56	4	93.3%
	125% (12.5)	120	109	11	90.8%
	150% (15)	140	140	0	100%
BZD	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%
	150% (450)	30	30	0	100%
COC	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	8	2	80%
	150% (450)	30	30	0	100%
MET	0% (0)	350	350	0	100%
	75% (750)	10	9	1	90%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
MTD	0% (0)	350	350	0	100%
	75% (225)	10	8	2	80%
	125% (375)	10	10	0	100%
	150% (450)	30	30	0	100%
PCP	0% (0)	350	350	0	100%
	50% (12.5)	10	10	0	100%
	125% (31.25)	10	9	1	90%
	150% (37.5)	30	30	0	100%
TCA	0% (0)	350	350	0	100%
	50% (500)	10	10	0	100%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
THC	0% (0)	350	350	0	100%
	50% (25)	10	10	0	100%
	125% (62.5)	10	8	2	80%
	150% (75)	30	30	0	100%
XTC	0% (0)	350	350	0	100%
	50% (250)	10	10	0	100%
	125% (625)	10	9	1	90%
	150% (750)	30	30	0	100%
MOR	0% (0)	350	350	0	100%
	50% (100)	10	10	0	100%
	125% (2500)	10	8	2	80%
	150% (3000)	30	30	0	100%
OXY	0% (0)	350	350	0	100%

<b>Drug</b>	<b>Cutoff Concentration% (ng/ml)</b>	<b>Number of studies</b>	<b>Correctly interpreted</b>	<b>Incorrectly interpreted</b>	<b>% agreement</b>
	50% (150)	10	10	0	100%
	125% (375)	10	8	2	80%
	150% (450)	30	30	0	100%

**Summary of Results for the Panel Format**

<b>Drug</b>	<b>Cutoff Concentration% (ng/ml)</b>	<b>Number of studies</b>	<b>Correctly interpreted</b>	<b>Incorrectly interpreted*</b>	<b>% agreement</b>
AMP	0% (0)	350	350	0	100%
	75% (750)	10	9	1	90%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
BAR	0% (0)	350	350	0	100%
	75% (150)	10	9	1	90%
	125% (250)	10	8	2	80%
	150% (300)	30	30	0	100%
BUP	0% (0)	20	20	0	100%
	50% (5)	60	60	0	100%
	75% (7.5)	60	55	5	91.7%
	125% (12.5)	120	112	8	93.3%
	150% (15)	140	140	0	100%
BZD	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%
	150% (450)	30	30	0	100%
COC	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%
	150% (450)	30	30	0	100%
MET	0% (0)	350	350	0	100%
	75% (750)	10	8	2	80%
	125% (1250)	10	10	0	100%
	150% (1500)	30	30	0	100%
MTD	0% (0)	350	350	0	100%
	75% (225)	10	9	1	90%
	125% (375)	10	9	1	90%
	150% (450)	30	30	0	100%
PCP	0% (0)	350	350	0	100%
	50% (12.5)	10	10	0	100%
	125% (31.25)	10	9	1	90%

<b>Drug</b>	<b>Cutoff Concentration% (ng/ml)</b>	<b>Number of studies</b>	<b>Correctly interpreted</b>	<b>Incorrectly interpreted*</b>	<b>% agreement</b>
	150% (37.5)	30	30	0	100%
TCA	0% (0)	350	350	0	100%
	50% (500)	10	10	0	100%
	125% (1250)	10	9	1	90%
	150% (1500)	30	30	0	100%
THC	0% (0)	350	350	0	100%
	50% (25)	10	10	0	100%
	125% (62.5)	10	8	2	80%
	150% (75)	30	30	0	100%
XTC	0% (0)	350	350	0	100%
	50% (250)	10	10	0	100%
	125% (625)	10	9	1	90%
	150% (750)	30	30	0	100%
MOR	0% (0)	350	350	0	100%
	50% (100)	10	10	0	100%
	125% (2500)	10	9	1	90%
	150% (3000)	30	30	0	100%
OXY	0% (0)	350	350	0	100%
	50% (150)	10	10	0	100%
	125% (375)	10	8	2	80%
	150% (450)	30	30	0	100%

No invalid test results were obtained during the lay user study.

All participants completed questionnaires after they completed the testing. The majority of participants indicated they could understand the labeling without difficulty.

A Flesh-Kincaid reading analysis revealed that package inserts for both formats had a reading grade level of 7.

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.