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

A. 510(k) Number:

k173303

B. Purpose for Submission:

Modification of the read time and cup format of a previously cleared device

C. Measurands:

Amphetamine, Barbiturates, Buprenorphine, Benzodiazepine, Cocaine, Methamphetamine, Methadone, Phencyclidine, Tricyclic antidepressants, Cannabinoids (Marijuana), 3,4-Methylene-dioxymethamphetamine (MDMA), Morphine, and Oxycodone.

D. Type of Test:

Qualitative, lateral flow immunochromatographic assay

E. Applicant:

ALFA Scientific Designs, Inc.

F. Proprietary and Established Names:

INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use)
INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use)

G. Regulatory Information:

Product Code	Regulation Name	Regulation Section	Panel
DKZ, NFT	Amphetamine test system	862.3100	Toxicology (91)
JXM, NFV	Benzodiazepine test system	862.3170	
DIO, NFY	Cocaine and cocaine metabolites test system	862.3250	
LDJ, NFW	Cannabinoid test system	862.3870	
DJC, NGG	Methamphetamine test system	862.3610	
LCM, NGM	Phencyclidine test system	Unclassified	
DIS, PTH	Barbiturate test system	862.3150	
DNK, NGI	Morphine test system	862.3640	
DJR, PTG	Methadone test system	862.3620	
LFG, QAW	Tricyclic antidepressant drugs test system	862.3910	
DJG, NGL	Opiate test system	862.3650	

H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use

2. Indication(s) for use:

   The INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use) device is a rapid, qualitative immunoassay device for the detection of one or more drugs or metabolites at the designated cutoff concentrations in human urine. The device can detect up to 13 drugs or their metabolites:

Analyte	Calibrator	Cutoff (ng/mL)
Amphetamines	d-Amphetamine	1000
Barbiturates	Secobarbital	200
Buprenorphine	Buprenorphine	10
Benzodiazepines	Oxazepam	300
Cocaine	Benzoylecgonine	300
Methamphetamine	d-Methamphetamine	1000
Methadone	Methadone	300
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Nortriptyline	1000
Cannabinoids	11-nor-Δ9-THC-9-COOH	50
MDMA	Methylenedioxy-methamphetamine	500
Morphine	Morphine	2000
Oxycodone	Oxycodone	300

These assays may yield positive results when barbiturates, benzodiazepines, or tricyclic antidepressants are ingested at or above therapeutic doses. There are no uniformly recognized cutoff levels for barbiturates, benzodiazepines, or tricyclic antidepressants in urine. The assays are not intended to distinguish between prescription use or abuse of these drugs.

This device provides 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.

The INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use) device is a rapid, qualitative immunoassay device for the detection of one or more drugs

or metabolites at the designated cutoff concentrations in human urine. The device can detect up to 13 drugs or their metabolites:

Analyte	Calibrator	Cutoff (ng/mL)
Amphetamines	d-Amphetamine	1000
Barbiturates	Secobarbital	200
Buprenorphine	Buprenorphine	10
Benzodiazepines	Oxazepam	300
Cocaine	Benzoylecgonine	300
Methamphetamine	d-Methamphetamine	1000
Methadone	Methadone	300
Phencyclidine	Phencyclidine	25
Tricyclic Antidepressants	Nortriptyline	1000
Cannabinoids	11-nor-Δ9-THC-9-COOH	50
MDMA	Methylenedioxy-methamphetamine	500
Morphine	Morphine	2000
Oxycodone	Oxycodone	300

These assays may yield positive results when barbiturates, benzodiazepines, or tricyclic antidepressants are ingested at or above therapeutic doses. There are no uniformly recognized cutoff levels for barbiturates, benzodiazepines, or tricyclic antidepressants in urine. The assays are not intended to distinguish between prescription use or abuse of these drugs.

This device provides 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.

3. Special conditions for use statement(s):

The INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use) is for over-the-counter use. The INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use) is for prescription use.

4. Special instrument requirements:

Not applicable.

I. Device Description:

The INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use) and INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use) are one-step lateral flow chromatographic immunoassays. The devices are identical except for the intended use (one for over the counter use and one for prescription use). 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. The results may be read between 2 and 120 minutes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

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

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

   k152122

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Qualitative detection of drugs of abuse in urine
Test Principle	Same	Lateral flow immunochromatographic
Matrix	Same	Urine
Number of strips per device	Same	1 – 13 depending upon configuration
Analyte cutoffs (ng/mL)	Same	Amphetamines – 1000 Barbiturates – 200 Buprenorphine – 10 Benzodiazepines – 300 Cocaine – 300 Methylenedioxymethamphetamine (MDMA) – 500 Methamphetamine – 1000 Methadone – 300 Morphine – 2000 Oxycodone – 300 Phencyclidine – 25

Similarities		
Item	Device	Predicate
		Tricyclic Antidepressants – 1000 Cannabinoids – 50
Shelf life	Same	24 months
Storage conditions	Same	15^{o} – 30^{o} C

Differences		
Item	Device	Predicate
Sample application procedure	User urinates into cup and urine contacts the test strips immediately.	User urinates into cup, but the urine sample does not contact test strips until a knob is pushed, allowing the sample to flow to the bottom of the cup.
Read Time	2 – 120 minutes	4 – 7 minutes

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):

The two devices are identical except for the intended use (one for over the counter use and one for prescription use) so only one type of device was used to collect the performance data below.

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Each analyte for the precision study was tested at the following concentrations: Negative, -75%, -50%, -25%, cutoff, +25%, +50%, +75%, and +100% of the cutoff for each analyte. The panels were blinded and randomized prior to testing. Testing was performed using three lots of test strips and was performed by 10 operators over ten non-consecutive days, and the results of this testing are summarized as follows for each analyte.

   Amphetamines (AMP)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
250	-75%	50/0	50/0	50/0
500	-50%	50/0	50/0	50/0
750	-25%	50/0	50/0	50/0
1000	cutoff	2/48	1/49	1/49
1250	+25%	0/50	0/50	0/50
1500	+50%	0/50	0/50	0/50
1750	+75%	0/50	0/50	0/50
2000	+100%	0/50	0/50	0/50

   Barbiturates (BAR)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
50	-75%	50/0	50/0	50/0
100	-50%	50/0	50/0	50/0
150	-25%	50/0	50/0	50/0
200	cutoff	1/49	3/47	2/48
250	+25%	0/50	0/50	0/50
300	+50%	0/50	0/50	0/50
350	+75%	0/50	0/50	0/50
400	+100%	0/50	0/50	0/50

Buprenorphine (BUP)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
2.5	-75%	50/0	50/0	50/0
5	-50%	50/0	50/0	50/0
7.5	-25%	50/0	50/0	50/0
10	cutoff	1/49	2/48	2/48
12.5	+25%	0/50	0/50	0/50
15	+50%	0/50	0/50	0/50
17.5	+75%	0/50	0/50	0/50
20	+100%	0/50	0/50	0/50

Benzodiazepines (BZD)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	2/48	2/48	2/48
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

Cocaine (COC)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	1/49	2/48	1/49
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

Methamphetamine (MET)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
250	-75%	50/0	50/0	50/0
500	-50%	50/0	50/0	50/0
750	-25%	50/0	50/0	50/0
1000	cutoff	1/49	2/48	1/49
1250	+25%	0/50	0/50	0/50
1500	+50%	0/50	0/50	0/50
1750	+75%	0/50	0/50	0/50
2000	+100%	0/50	0/50	0/50

Methadone (MTD)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	2/48	2/48	2/48
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

Phencyclidine (PCP)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
6.25	-75%	50/0	50/0	50/0
12.5	-50%	50/0	50/0	50/0
18.75	-25%	50/0	50/0	50/0
25	cutoff	1/49	2/48	2/48
31.25	+25%	0/50	0/50	0/50
37.5	+50%	0/50	0/50	0/50
43.75	+75%	0/50	0/50	0/50
50	+100%	0/50	0/50	0/50

Tricyclic Antidepressants (TCA)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
250	-75%	50/0	50/0	50/0
500	-50%	50/0	50/0	50/0
750	-25%	50/0	50/0	50/0
1000	cutoff	3/47	2/48	1/49
1250	+25%	0/50	0/50	0/50
1500	+50%	0/50	0/50	0/50
1750	+75%	0/50	0/50	0/50
2000	+100%	0/50	0/50	0/50

Cannabinoids (THC)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
12.5	-75%	50/0	50/0	50/0
25	-50%	50/0	50/0	50/0
37.5	-25%	50/0	50/0	50/0
50	cutoff	1/49	1/49	1/49
62.5	+25%	0/50	0/50	0/50
75	+50%	0/50	0/50	0/50
87.5	+75%	0/50	0/50	0/50
100	+100%	0/50	0/50	0/50

MDMA (XTC)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
125	-75%	50/0	50/0	50/0
250	-50%	50/0	50/0	50/0
375	-25%	50/0	50/0	50/0
500	cutoff	3/47	2/48	2/48
625	+25%	0/50	0/50	0/50
750	+50%	0/50	0/50	0/50
875	+75%	0/50	0/50	0/50
1000	+100%	0/50	0/50	0/50

Morphine (MOR)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
500	-75%	50/0	50/0	50/0
1000	-50%	50/0	50/0	50/0
1500	-25%	50/0	50/0	50/0
2000	cutoff	2/48	1/49	2/48
2500	+25%	0/50	0/50	0/50
3000	+50%	0/50	0/50	0/50
3500	+75%	0/50	0/50	0/50
4000	+100%	0/50	0/50	0/50

Oxycodone (OXY)

Concentration (ng/mL)	% of cutoff	Results (Neg/Pos) Lot 1	Results (Neg/Pos) Lot 2	Results (Neg/Pos) Lot 3
0	0	50/0	50/0	50/0
75	-75%	50/0	50/0	50/0
150	-50%	50/0	50/0	50/0
225	-25%	50/0	50/0	50/0
300	cutoff	2/48	2/48	2/48
375	+25%	0/50	0/50	0/50
450	+50%	0/50	0/50	0/50
525	+75%	0/50	0/50	0/50
600	+100%	0/50	0/50	0/50

b. *Linearity/assay reportable range:*

Not applicable.

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

This device has internal process controls. A control line appears in the control region confirming that sufficient sample volume has been applied to the test strip and that the sample has migrated correctly on the test strip. Users are informed that the test is invalid if the colored line does not 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 two years (24 months) when stored at 15–30º C.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Analytical specificity for this device was previously reviewed in k152122.

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:

The accuracy performance of this device to a comparator method was previously reviewed in k152122.

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):

In order to evaluate the modified read time and cup, a lay user study was performed. A total of four-hundred (400) participants were recruited. Each participant was provided one (1) package insert, one (1) blind labeled test solution, and one (1) test device. Test solutions were randomly assigned to participants, one for each. Every participant performed testing using the device and only instructions provided in the device labeling. Following testing, users completed a study questionnaire to assess usability and user comprehension, and the results from this questionnaire were found to be acceptable. Participants aged 18 and over, with diverse educational backgrounds, were recruited. Results from the lay user testing are provided in the below table:

Drug (cutoff ng/ml)	Cutoff Concentration% (ng/ml)	Number of samples	Negative	Positive
AMP (1000)	0% (0)	350	350	0
	75% (750)	10	9	1
	125% (1250)	10	1	9
	150% (1500)	30	0	30
BAR (200)	0% (0)	350	350	0
	75% (150)	10	9	1
	125% (250)	10	1	9
	150% (300)	30	0	30
BUP (10)	0% (0)	20	20	0
	50% (5)	60	60	0
	75% (7.5)	60	57	3
	125% (12.5)	120	9	111
	150% (15)	140	0	140
BZD (300)	0% (0)	350	350	0
	75% (225)	10	9	1
	125% (375)	10	1	9
	150% (450)	30	0	30
COC (300)	0% (0)	350	350	0
	75% (225)	10	9	1
	125% (375)	10	0	10
	150% (450)	30	0	30
MET (1000)	0% (0)	350	350	0
	75% (750)	10	9	1
	125% (1250)	10	1	9
	150% (1500)	30	0	30
MTD (300)	0% (0)	350	350	0
	75% (225)	10	8	2
	125% (375)	10	0	10
	150% (450)	30	0	30
PCP (25)	0% (0)	350	350	0
	75% (18.75)	10	10	0
	125% (31.25)	10	1	9
	150% (37.5)	30	0	30
TCA (1000)	0% (0)	350	350	0
	75% (750)	10	9	1
	125% (1250)	10	1	9
	150% (1500)	30	0	30

Drug (cutoff ng/ml)	Cutoff Concentration% (ng/ml)	Number of samples	Negative	Positive
THC (50)	0% (0)	350	350	0
	75% (37.5)	10	10	0
	125% (62.5)	10	2	8
	150% (75)	30	0	30
XTC (MDMA) (500)	0% (0)	350	350	0
	75% (37.5)	10	10	0
	125% (625)	10	1	9
	150% (750)	30	0	30
MOR (2000)	0% (0)	350	350	0
	75% (1500)	10	10	0
	125% (2500)	10	2	8
	150% (3000)	30	0	30
OXY (300)	0% (0)	350	350	0
	75% (225)	10	10	0
	125% (375)	10	2	8
	150% (450)	30	0	30

A study to evaluate the new read time was performed; accurate results were obtained when using the device with the new read time (2 – 120 minutes).

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.