

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

A. 510(k) Number:

k100051

B. Purpose for Submission:

Modification of a cleared device. Adding OTC use for morphine/opiates 300, oxycodone 100, and oxycodone 300.

C. Measurand:

Morphine/opiates 300, oxycodone 100, and oxycodone 300

D. Type of Test:

Qualitative lateral flow immunoassay

E. Applicant:

Alfa Scientific Designs, Inc.

F. Proprietary and Established Names:

Instant-View Drug of Abuse Urine Cassette Test

Instant-View Drug of Abuse Urine Cup Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	862.3650 – Opiate Test System	91-Toxicology
NGI	Class II	862.3640 - Morphine Test, Over the Counter	91-Toxicology

H. Intended Use:

1. Intended use(s):
See indications for use statement below.

2. Indication(s) for use:

The Drug of Abuse Urine (Cassette/Cup) Test is a rapid qualitative immunoassay for the detection of potential abuse of one or more drugs: Morphine/Opiates, and Oxycodone (see list below). The device is intended for in vitro diagnostic home use.

Abbreviation	Test	Calibrator	Cutoff
MOR/OPI300	Morphine/Opiates	Morphine	300 ng/mL
OXY100	Oxycodone	Oxycodone	100 ng/mL
OXY300	Oxycodone	Oxycodone	300 ng/mL

This assay provides only preliminary results. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) 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 indicated.

3. Special conditions for use statement(s):

For over the counter (OTC) use

4. Special instrument requirements:

Not applicable

I. Device Description:

The device is available in a cup or cassette format. The device consists of any combination between one (1) to three (3) individual test strip(s) for the drug(s) being tested. Each test strip in the device consists of 1) a colored 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 colored band during test regardless of the presence of the drug.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Alpha Scientific *INSTANT-VIEW*[®] Oxycodone Urine Test
Alpha Scientific *INSTANT-VIEW*[®] Morphine (300) Urine Test

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

k063545, k060527

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
<u>Indication(s) for use</u>	A rapid qualitative immunoassay for the detection of potential abuse of one or more drugs	Same
Assay Technology	one-step lateral-flow chromatographic immunoassays	Same
Results	Qualitative	Same
Format	Cup and cassette	Same
Quality Control	Built in QC	Same

Differences		
Item	Device	Predicate
Intended Use	OTC Use	Prescription Use

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

None Referenced

L. Test Principle:

The 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 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 of certain testing steps. It should always appear as a colored band regardless of the presence of the drug if enough sample volume has been added to the test and if sample has correctly migrated up the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Established in k063545 and k060527.

b. Linearity/assay reportable range:

Established in k063545 and k060527.

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

Established in k063545 and k060527.

d. Detection limit:

Established in k063545 and k060527.

e. Analytical specificity:

Established in k063545 and k060527.

f. Assay cut-off:

Established in k063545 and k060527.

2. Comparison studies:

a. Method comparison with predicate device:

Established in k063545 and k060527.

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):

OTC Accuracy study – cup format

Over the counter (OTC) accuracy studies were carried out at three independent sites. A total of 136 OTC users participated in the study. 40-50 OTC users ranging in age from 18 to 72 with diverse educational and professional backgrounds participated at each site. 38% of the participants were female and 62% were male.

Urine samples were prepared at the concentrations in the table below by spiking drug(s) 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 insert and 3 blind labeled samples and devices. Each participant tested 3 samples for the 3 drugs. There was no significant difference between the results at the 3 sites so data were pooled and analyzed. The results are summarized below.

Test Results for Cup format

Instant-View Cup		Number of samples	OTC User		Agreement With GC/MS	Accuracy
Drug	Concentration		Negative	Positive		
MOR300	<50% cutoff	211	211	0	100%	98.78%
	50% cutoff	41	41	0	100%	
	75% cutoff	41	38	3	92.7%	
	125% cutoff	39	0	39	100%	
	150% cutoff	34	0	34	100%	
	>150% cutoff	42	0	42	100%	
OXY100	<50% cutoff	84	84	0	100%	97.9%
	50% cutoff	44	44	0	100%	
	75% cutoff	44	43	1	97.7%	
	125% cutoff	39	4	35	89.7%	
	150% cutoff	41	0	41	100%	
	>150% cutoff	156	0	156	100%	
OXY300	<50% cutoff	211	211	0	100%	97.16%
	50% cutoff	41	41	0	100%	
	75% cutoff	41	34	7	82.93%	
	125% cutoff	39	0	39	100%	
	150% cutoff	34	0	34	100%	
	>150% cutoff	42	0	42	100%	

All OTC study participants completed questionnaires after they performed the test and recorded their results. The questionnaires covered evaluation of the package insert regarding the intended user, the directions for performing the test, the ease of performing the test, directions for interpreting the results, and ease of interpretation of the results. These questionnaires demonstrated that the test instructions were easy to understand and that the testing procedure was easy to perform and the results were easy to read.

OTC Accuracy study – Cassette format

Over the counter (OTC) accuracy studies were carried out at three independent sites. A total of 128 OTC users participated in the study. 39-45 OTC users ranging in age from 18 to 60 with diverse educational and professional backgrounds participated at each site. 55% of the participants were female and 45% were male.

Urine samples were prepared at the concentrations in the table below by spiking drug(s) 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 insert and 3 blind labeled samples and devices. Each participant tested 3 samples for the 3 drugs. There was no significant difference between the results at the 3 sites so data were pooled and analyzed. The results are summarized below.

Test Results - cassette device

Instant-View Cassette		Number of samples	OTC User		Agreement With GC/MS	Accuracy
Drug	Concentration		Negative	Positive		
MOR300	<50% cutoff	212	212	0	100%	98.7%
	50% cutoff	29	29	0	100%	
	75% cutoff	52	49	3	94.2%	
	125% cutoff	47	1	46	97.9%	
	150% cutoff	27	0	27	100%	
	>150% cutoff	17	0	17	100%	
OXY100	<50% cutoff	101	101	0	100%	97.8%
	50% cutoff	27	27	0	100%	
	75% cutoff	47	45	2	95.7%	
	125% cutoff	46	4	42	91.3%	
	150% cutoff	30	0	30	100%	
	>150% cutoff	133	0	133	100%	
OXY300	<50% cutoff	221	221	0	100%	97.7%
	50% cutoff	30	30	0	100%	
	75% cutoff	45	43	2	95.6%	
	125% cutoff	43	4	39	90.7%	
	150% cutoff	28	0	28	100%	
	>150% cutoff	17	0	17	100%	

All OTC study participants completed questionnaires after they performed the test and recorded their results. The questionnaires covered evaluation of the package insert regarding the intended user, the directions for performing the test, the ease of performing the test, directions for interpreting the results, and

ease of interpretation of the results. These questionnaires demonstrated that the test instructions were easy to understand and that the testing procedure was easy to perform and the results were easy to read.

The temperature strip that is part of the test cup was evaluated by the participants at three sites. The participants that performed the temperature evaluation were the same participants that performed the cup format evaluation. Water samples were adjusted to different temperatures and added to the sample cups. Participants read the temperature on the strip on the cup and recorded the results. The testing monitor then immediately measured and recorded the water temperature. The results demonstrated that 95.3% of the participants accurately identified the temperature of the water using the temperature strip on the test cup.

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.