

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

A. 510(k) Number:

k082898

B. Purpose for Submission:

This submission is for the addition of an over-the-counter (OTC) claim for previously cleared prescription devices: k040464 (THC, COC, OPI300, OXY, BAR, BZO), k031497 (MDMA, BAR, BZO, MTD, TCA), k023109 (PCP), k023101 (MTH), k023104 (AMP), k023047 (OPI2000), k022954 (COC) and k022955 (THC).

C. Measurand:

Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Opiates (OPI), Barbiturates (BAR), Benzodiazepines (BZD), Methadone (MTD), Oxycodone (OXY), MDMA, and Tricyclic Antidepressants (TCA).

D. Type of Test:

Qualitative Lateral Flow Immunoassay

E. Applicant:

Amedica Biotech Inc.

F. Proprietary and Established Names:

Amedica Home Drug Test Cup

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NGL	II	862.3650, Test, Opiates, Over-the-Counter	91 (Tox)
NFT	II	862.3100, Test, Amphetamine, Over-the-Counter	91 (Tox)
NFY	II	862.3250, Test, Cocaine and Cocaine Metabolites, Over-the-Counter,	91 (Tox)
NGG	II	862.3610, Test,	91 (Tox)

		Methamphetamine, Over-the-Counter	
DIS	II	862.3120, <u>Enzyme immunoassay, Barbiturate</u>	91 (Tox)
NFV	II	862.3170, <u>Test, Benzodiazepine, over the counter</u>	91 (Tox)
DJR	II	862.3620, Enzyme Immunoassay, Methadone	91 (Tox)
LCM	Unclassified [510(k) required]	Unclassified - <u>Enzyme immunoassay, phencyclidine</u>	91 (Tox)
LFG	II	862.3910, Thin layer chromatography, tricyclic antidepressant drugs	91 (Tox)
NFW	II	862.3870, Test, Cannabinoids, Over-the-Counter	91 (Tox)

H. Intended Use:

1. Intended use(s):

See indications for use section below.

2. Indication(s) for use:

The Amedica Home Drug Test Cup is an *in vitro* diagnostic test for the rapid detection of the following drugs in human urine.

<u>Drug</u>	<u>Analyte</u>	<u>Cutoff</u>	<u>Device Code</u>
Marijuana	THC	50 ng/mL	THC
Cocaine	Benzoylcegonine	300 ng/mL	COC
Amphetamine	Amphetamine	1000 ng/mL	AMP
Methamphetamine	Methamphetamine	1000 ng/mL	MET
Opiates	Morphine	2000 ng/mL	OPI
Opiates300	Morphine	300 ng/ml	OPI300
Phencyclidine	Phencyclidine	25 ng/mL	PCP
Barbiturates	Secobarbital	300 ng/mL	BAR
Benzodiazepines	Oxazepam	300 ng/mL	BZD
Methadone	Methadone	300 ng/mL	MTD
Oxycodone	Oxycodone	100 ng/mL	OXY
MDMA	MDMA	500 ng/mL	MDMA
Tricyclic Antidepressants	Nortriptyline	1000 ng/mL	TCA

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 prescription drugs are ingested, even at or above therapeutic doses. There are no uniformly recognized drug cutoffs for barbiturates, benzodiazepine, and tricyclic antidepressants in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) 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):

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 prescription drugs are ingested, even at or above therapeutic doses. There are no uniformly recognized drug cutoffs for barbiturates, benzodiazepine, and tricyclic antidepressants in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) 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.

4. Special instrument requirements:

Not applicable (N/A).

I. Device Description:

The Amedica Home Drug Test Cup is a cup capable of measuring all 12 drugs listed in the intended use. The Amedica Home Drug Test Cup also includes user

instructions, collection device and mailing information for shipping preliminarily positive urine specimens to the laboratory for confirmation.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Amedica Drug Screen Test Cup

2. Predicate K number(s):

k063379, k061556, k040464, k031497, k023109, k023101, k023104, k023047, k022954 and k022955

3. Comparison with predicate:

The submission is for identical test strips as the predicate devices. The differences are the target population (OTC vs. prescription use) and the number of drugs detected.

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

None referenced.

L. Test Principle:

The Amedica Drug Screen Test Cup 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 antibody-coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region. The colored line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody. There is a specific reagent strip for each analyte. Each strip in the device contains a procedural control that appears in the control line region indicating that the sample has migrated properly on the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

This submission is for an OTC claim. Performance characteristics for each of the drugs are found in the following 510(k) numbers:: k040464 (THC, COC, OPI300, OXY, BAR, BZO), k031497 (MDMA, BAR, BZO, MTD, TCA), k023109 (PCP), k023101 (MTH), k023104 (AMP), k023047 (OPI2000), k022954 (COC) and k022955 (THC).

a. Precision/Reproducibility:

See k040464 (THC, COC, OPI300, OXY, BAR, BZO), k031497 (MDMA, BAR, BZO, MTD, TCA), k023109 (PCP), k023101 (MTH), k023104 (AMP), k023047 (OPI2000), k022954 (COC) and k022955 (THC).

b. Linearity/assay reportable range:

See k040464 (THC, COC, OPI300, OXY, BAR, BZO), k031497 (MDMA, BAR, BZO, MTD, TCA), k023109 (PCP), k023101 (MTH), k023104, (AMP), k023047 (OPI2000), k022954 (COC) and k022955 (THC).

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

This device has internal process controls. Each strip in the device contains a procedural control that appears in the control line region indicating that the sample has migrated properly on the test strip. The sponsor informs the user not to interpret the test if a colored line failed to appear in the control region. External controls are not supplied with this device.

d. Detection limit:

See k040464 (THC, COC, OPI300, OXY, BAR, BZO), k031497 (MDMA, BAR, BZO, MTD, TCA), k023109 (PCP), k023101 (MTH), k023104 (AMP), k023047 (OPI2000), k022954 (COC) and k022955 (THC).

e. Analytical specificity:

See k040464 (THC, COC, OPI300, OXY, BAR, BZO), k031497 (MDMA, BAR, BZO, MTD, TCA), k023109 (PCP), k023101 (MTH), k023104, (AMP), k023047 (OPI2000), k022954 (COC) and k022955 (THC).

f. Assay cut-off:

See k040464 (THC, COC, OPI300, OXY, BAR, BZO), k031497 (MDMA, BAR, BZO, MTD, TCA), k023109 (PCP), k023101 (MTH), k023104 (AMP), k023047 (OPI2000), k022954 (COC) and k022955 (THC).

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a lay user study with 100 lay persons in three locations: Tennessee, Kentucky and California. Fifty-four females and forty-eight males between 18 and 71 years of age were tested. Fifty-one participants had a high school education or less, forty-eight participants had

completed college courses. None of the participants had experience with a point of care drug testing product. Each participant was given a pre and post-study questionnaire. The pre-study questionnaire collected personal information about each participant. Test samples were prepared to contain a strong negative (0 % of the cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a weak positive (125% of cutoff), a strong positive (150% of cutoff) and a very strong positive (300% of the cutoff) for each drug. The test specimens were prepared at concentrations shown below. Pure drug or metabolite was spiked into drug free human urine. All specimens were verified by GC/MS. 3 users tested six samples, 5 users tested five samples, 92 users tested three samples, one user tested one two samples and one user tested one sample. There were 322 total observations.

Drug	Cutoff (ng/ml)	Results	Drug Concentration						
			Negative	50% of C/O	75% of C/O	125% of C/O	150% of C/O	300% of C/O	Total % correct
THC	50	Negative	179	19	12	5	0	0	96%
		Positive	0	0	5	15	18	20	
		Total	179	19	17	20	18	20	
		Agreement	100%	100%	72%	75%	100%	100%	
MTD	50	Negative	180	19	11	7	0	0	95%
		Positive	0	0	7	12	17	20	
		Total	180	19	18	19	17	20	
		Agreement	100%	100%	63%	63%	100%	100%	
COC	50	Negative	180	20	12	5	0	0	96%
		Positive	0	0	5	14	18	19	
		Total	180	20	17	19	18	19	
		Agreement	100%	100%	72%	74%	100%	100%	
BZO	50	Negative	178	19	14	8	0	0	95%
		Positive	0	0	6	12	17	19	
		Total	178	19	20	20	17	19	
		Agreement	100%	100%	70%	60%	100%	100%	
OPI	50	Negative	167	14	7	1	0	0	98%
		Positive	0	0	3	8	15	16	
		Total	167	14	10	9	15	16	
		Agreement	100%	100%	70%	89%	100%	100%	

OPI300	50	Negative	25	10	7	3	0	0	93%
		Positive	0	0	3	12	15	15	
		Total	25	10	10	15	15	15	
		Agreement	100%	100%	70%	80%	100%	100%	
OXY	50	Negative	180	19	12	5	0	0	96%
		Positive	0	0	6	12	20	19	
		Total	180	19	18	17	20	19	
		Agreement	100%	100%	67%	71%	100%	100%	
PCP	50	Negative	182	19	14	3	0	0	97%
		Positive	0	0	4	16	18	17	
		Total	182	19	18	19	18	17	
		Agreement	100%	100%	78%	84%	100%	100%	
TCA	50	Negative	179	19	12	7	0	0	95%
		Positive	0	0	7	12	18	19	
		Total	179	19	19	19	18	19	
		Agreement	100%	100%	63%	63%	100%	100%	
MDMA	50	Negative	176	20	14	5	0	0	96%
		Positive	0	0	6	14	19	19	
		Total	176	20	20	19	19	19	
		Agreement	100%	100%	70%	74%	100%	100%	
MET	50	Negative	175	20	14	5	0	0	96%
		Positive	0	0	5	15	20	19	
		Total	175	20	19	20	20	19	
		Agreement	100%	100%	75%	75%	100%	100%	
AMP	50	Negative	176	20	13	4	0	0	97%
		Positive	0	0	5	16	19	20	
		Total	176	20	18	20	19	20	
		Agreement	100%	100%	74%	80%	100%	100%	
BAR	50	Negative	177	20	12	5	0	0	96%
		Positive	0	0	6	15	18	20	
		Total	177	20	18	20	18	20	
		Agreement	100%	100%	68%	75%	100%	100%	

A Flesh-Kincaid reading analysis was performed on the package insert and

the score revealed a reading grade level of 7.4 .

The post-study questionnaire was used to determine if the lay users understood the test instruction and the meaning of the results. Consumers were asked questions about the test, control line and confirmation of results. The results were acceptable. The sponsor conducted a lay-user study to evaluate the temperature strips that are permanently affixed to the Amedica Drug Screen Test Cup. Twenty-one participants between the ages of 18 and 64 years of age tested their own urine samples and recorded what temperature showed up as green on the cup. The participants' results were verified by the professional. All 21 users' results were correct and showed that the users were able to read and understand the affixed temperature strips. Participants were asked questions about how to run the test, ease of use, and how to use the results of the temperature strip. The responses were 100% correct. *b.*

Matrix comparison:

Not applicable. The assay is intended for urine samples.

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):

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 Part 809.10.

O. Conclusion:

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