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

A. 510(k) Number:

k152590

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Methamphetamine, Morphine, Cocaine, Marijuana

D. Type of Test:

Qualitative immunoassay

E. Applicant:

Coretests, Inc.

F. Proprietary and Established Names:

ACCU NEWS Drug Screening Test Card

ACCU NEWS Drug Screening Urine Cup

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LDJ	II	862.3870, Cannabinoid Test System	91-Toxicology
DIO	II	862.3250, Cocaine and Cocaine Metabolite Test System	91-Toxicology
DNK	II	862.3640, Morphine Test System	91-Toxicology
LAF	II	862.3610, Methamphetamine Test System	91-Toxicology
DKZ	II	862.3100, Amphetamine Test System	91-Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The ACCU NEWS Drug Screening Test Card and Urine Cup are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Cocaine, Marijuana, Methamphetamine and Morphine in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgnonine	300
Methamphetamine	MET	d-Methamphetamine	1000
Morphine	MOP	Morphine	300
Marijuana	THC	11-Nor-Δ9-THC-9-COOH	50

   The ACCU NEWS Drug Screening Test Card and Urine Cup 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 used.

   This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers, 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.

3. Special conditions for use statement(s):

   For prescription and over-the-counter (OTC) use.

4. Special instrument requirements:

   Not applicable, these are are visually-read single-use devices.

I. Device Description:

These devices are for use with human urine only. The device is available in two different formats, 1) test card and 2) urine cup. They consist of:

1. One pouch containing the test device and desiccant (the desiccant is for storage purpose only)
2. A sample collection cup, a plastic specimen bag, a confirmation test label, and a pre-addressed mailer (for confirmation test)
3. An instruction sheet

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Innovacon Spectrum II Test Card/Test Card with Integrated Cups.

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

   K061718

3. Comparison with predicate:

Similarities and Differences				
Item	Predicate Device: Innovacon Spectrum II Test Card/Test Card with Integrated Cups (k061718)		Candidate Device: ACCU NEWS Drug Screening Test Card/Urine Cup (k152590)	
Intended use	For detection of drugs/drug metabolites in human urine to screen for drugs of abuse.		Same	
Specimen	Human urine		Same	
Results	Qualitative		Same	
Methodology	Competitive Lateral Flow Immunoassay		Same	
Intended Users	Prescription users		Prescription and over-the-counter (OTC) users	
Formats	Test Card and Urine Cup		Same	
Storage Temperature	2-30^{0}C (36-86^{0}F)		Same	
Analytes and Cutoff (ng/ml)	Amphetamine	1000/300	Amphetamine	1000
	Cocaine	300/150	Cocaine	300
	Methamphetamine	1000/500	Methamphetamine	1000
	Morphine	2000/300	Morphine	300
	Marijuana	50	Marijuana	50

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

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition

L. Test Principle:

The ACCU NEWS Drug Screening Test Card and ACCU NEWS Urine Cup test devices are rapid lateral flow immunoassays in which drug-protein conjugates in the device compete with drugs or drug metabolites that may be present in urine. On each test strip, a drug-protein conjugate is present in the test band of the membrane (known as the test region, T), and the anti-drug antibody-colloidal gold conjugate pads are at the forward end of the membrane. If target drugs are present in the urine specimen below its cut-off concentration, the solution of the colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible line in the test band indicates a negative result. If the target drug level exceeds its cut-off concentration, the drug/metabolite competes with drug-protein conjugates on the test and region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored drug antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result. A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

a. Precision/Reproducibility:

The precision performance of the test strips of the devices was evaluated using 3 lots of testing devices conducted by 3 operators. Urine samples were spiked with different drug concentrations: negative, -50%, -25%, cut-off, +25%, and +50% of cut-off concentrations. The drug concentrations in the urine sample were confirmed by GC/MS analysis. Samples were blind-labeled and randomly distributed among operators. The study was conducted over 4 to 10 days. The results are summarized below:Results for Test Card:

Target Drug	**Concentration Tested**	**Total of three operators**
		Neg/Pos
AMP (cutoff: 1000 ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	6/24
	+25% of cutoff	0/30
	+50% of cutoff	0/30
MET	Negative	30/0

Target Drug	Concentration Tested	Total of three operators
		Neg/Pos
(cutoff: 1000ng/ml)	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	10/20
	+25% of cutoff	0/30
	+50% of cutoff	0/30
MOP (cutoff: 300ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	7/23
	+25% of cutoff	0/30
	+50% of cutoff	0/30
COC (cutoff: 300ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	29/1
	Cutoff	21/9
	+25% of cutoff	1/29
	+50% of cutoff	0/30
THC (cutoff: 50ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	24/6
	+25% of cutoff	0/30
	+50% of cutoff	0/30

Results for Urine Cup:

Target Drug	Concentration Tested	Total of three operators
		Neg/Pos
AMP (cutoff: 1000 ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	16/14
	+25% of cutoff	0/30
	+50% of cutoff	0/30
MET (cutoff: 1000ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	14/16

Target Drug	Concentration Tested	Total of three operators
		Neg/Pos
	+25% of cutoff	1/29
	+50% of cutoff	0/30
MOP (cutoff: 300ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	17/13
	+25% of cutoff	2/28
	+50% of cutoff	0/30
COC (cutoff: 300ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	19/11
	+25% of cutoff	2/28
	+50% of cutoff	0/30
THC (cutoff: 50ng/ml)	Negative	30/0
	-50% of cutoff	30/0
	-25% of cutoff	30/0
	Cutoff	23/7
	+25% of cutoff	0/30
	+50% of cutoff	0/30

b. Linearity/assay reportable range:

Not applicable. These devices are intended for qualitative use only.

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

Stability: Device stability has been evaluated through accelerated studies. Protocols and acceptance criteria were reviewed and found to be acceptable to support the claims that the devices are stable for two years (24 months) when stored at 36-86^{o}F (2–30^{o} C).

Real-time stability protocols and acceptance criteria were reviewed and found to be acceptable. The real-time stability studies are ongoing.

d. Detection limit:

See Precision/Reproducibility section in M.1.a above.

e. Analytical specificity:

For each drug, specificity was evaluated by spiking various concentrations of structurally similar compounds into drug-free urine. Results are expressed as a

minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross-reactivity of those compounds is listed below:

Drug Test	Compound	Concentration Equivalent to the Cutoff (ng/mL)	Cross-Reactivity (%)
AMP	**d-Amphetamine**	**1000**	**100**
	d,l-Amphetamine	3,000	33.3
	l-Amphetamine	50,000	2
	d-Methamphetamine	>100,000	<1
	l-Methamphetamine	>100,000	<1
	d-Ephedrine	>100,000	<1
	l-Ephedrine	>100,000	<1
	d-Pseudoephedrine	>100,000	<1
	l-Pseudoephedrine	>100,000	<1
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	2500	40
	3,4-Methylenedioxythylamphetamine (MDEA)	>100,000	<1
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	<1
	Phentermine	25000	4
MET	**d-Methamphetamine**	**1000**	**100**
	l-Methamphetamine	100,000	1
	d-Amphetamine	>100,000	<1
	l-Amphetamine	>100,000	<1
	d-Ephedrine	>100,000	<1
	l-Ephedrine	>100,000	<1
	d-Pseudoephedrine	>100,000	<1
	l-Pseudoephedrine	>100,000	<1
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100,000	<1
	3,4-Methylenedioxythylamphetamine (MDEA)	50,000	2
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	25,000	4
	Chloroquine	50,000	2
	β-Phenylethylamine	50,000	2
	Trimethobenamide	10,000	10

Drug Test	Compound	Concentration Equivalent to the Cutoff (ng/mL)	Cross-Reactivity (%)
MOP	**Morphine**	**300**	**100**
	Codeine	300	100
	Ethylmorphine	300	100
	Heroin	300	100
	6-Monoacetylmorphine	300	100
	Hydrocodone	5,000	6
	Hydromorphone	5,000	6
	Morphine-3-β-glucuronide	1,000	30
	Oxycodone	100,000	<1
COC	**Benzoylecogonine**	**300**	**100**
	Cocaine HCl	750	40
	Cocaethylene	12,500	2.4
	Ecgonine	32,000	<1
	Norcocaine	100,000	<1
THC	**11-Nor-Δ9-Tetrahydrocannabinol carboxylic acid**	**50**	**100**
	11-Hydroxy-Δ9-Tetrahydrocannabinol	2,500	2
	Δ8-Tetrahydrocannabinol	7,500	<1
	Δ9-Tetrahydrocannabinol	10,000	<1
	Cannabinol	10,000	<1
	Cannabidiol	100,000	<1

The sponsor also evaluated whether various substances commonly found in human urine in physiological or pathological conditions would interfere with test results. The following compounds were spiked into drug positive or negative urine at a concentration of 100 ug/ml; no interference was detected.

Acetylsalicyclic Acid	Ethyl-p-aminobenzoate	Oxymetazoline
Aminopyrine	Erythromycin	Papaverine
Amoxicillin	β-Estradiol	Penicillin-G
Ampicillin	Fenoprofen	Perphenazine
Apomorphine	Furosemide	Phenacetin
Aspartame	Gentisic acid	Phenelzine
Atropine	Hemoglobin	L-Phenylephrine
Benzilic acid	Hydralazine	β-Phenylethylamine
Benzoic acid	Hydrochlorothiazide	Phenylpropanolamine
Bilirubin	Hydrocortisone	Prednisone
Caffeine	3-Hydroxytyramine	D,L-Propanolol
Chloral hydrate	D,L-Isoproterenol	D-Pseudoephedrine
Chloramphenicol	Isoxsuprine	Quinidine

Chlorothiazide	Ketoprofen	Quinine
D,L-Chlolrpheniramine	Labetalol	Ranitidine
Chlorpromazine	Loperamide	Salicyclic acid
Chloroquine	Meprobamate	Serotonin
Cholesterol	Nalidixic acid	Sulfamethazine
Clonidine	Naloxone	Tetrahydrozoline
Cortisone	Naltrexone	Thiamine
L-Cotinine	Methoxyphenamine	Thioridazine
Creatinine	Naproxen	D,L-Tyrosine
Deoxycortisterone	Niacinamide	Triamterene
Dextromethorphan	Nifedipine	Trifluoperazine
Diclofenac	Norethindrone	Trimethoprim
Diflunisal	D-Norpropoxyphene	Tyramine
Digoxin	Noscapine	D,L-Tryptophan
Diphenhydramine	D,L-Octopamine	Uric acid
Ecgonine methyl ester	Oxalic acid	Verapamil
L-ψ-Ephedrine	Oxolinic acid	Zomepirac

The sponsor tested the effects of varying pH and specific gravity on drug positive and negative urine. The pH and specific gravity-adjusted urine samples were found not to interfere with the tests at pH range from 3.0 to 9.0 and specific gravity range from 1.001 to 1.040.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration is described in the precision section, M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor performed the method comparison study by comparing the performance of the devices to GC/MS results. A total of 340 clinical urine samples were distributed and tested across three sites with two operators at each site. Urine samples were blind-labeled for the testing and drug concentrations were determined by GC/MS. Results are summarized below:

Method comparison data – Test Card

	No Drug Present	Near Cutoff Negative (between - 50% cutoff and	Near Cutoff Negative (between cutoff and +50%	High Positive (> +50% cutoff)	% Agreement with GC/MS		Overall% Agreement with GC/MS
					Negative	Positive	

			cutoff)	cutoff)				
AMP	+	0	1	9	40	98%	98%	98%
	-	40	9	1	0			
MET	+	0	1	8	40	98%	96%	97%
	-	40	9	2	0			
MOP	+	0	2	10	40	96%	100%	98%
	-	40	8	0	0			
COC	+	0	1	8	40	98%	96%	97%
	-	40	9	2	0			
THC	+	0	0	8	40	100%	96%	98%
	-	40	10	2	0			

Summary of Discordant Results – Test Card:

Sample	Dug Test	Results Recorded	GC/MS Value (ng/mL)
844591	AMP 1000	Positive	952
545390	AMP 1000	Negative	1030
960940	MET 1000	Positive	982
860829	MET 1000	Negative	1054
610670	MET 1000	Negative	1060
572595	MOP 300	Positive	284
898906	MOP 300	Positive	286
699527	COC 300	Positive	285
710595	COC 300	Negative	322
491069	COC 300	Negative	330
494372	THC 50	Negative	54.3
801073	THC 50	Negative	55.0

Method comparison data – Urine Cup

		No Drug Present	Near Cutoff Negative (between - 50% cutoff and cutoff)	Near Cutoff Negative (between cutoff and +50% cutoff)	High Positive (> +50% cutoff)	% Agreement with GC/MS		Overall% Agreement with GC/MS
						Negative	Positive	
AMP	+	0	1	9	40	98%	98%	98%
	-	40	9	1	0			
MET	+	0	1	8	40	98%	96%	97%
	-	40	9	2	0			
MOP	+	0	2	10	40	96%	100%	98%

	-	40	8	0	0			
COC	+	0	0	8	40	100%	96%	98%
	-	40	10	2	0			
THC	+	0	0	8	40	100%	96%	98%
	-	40	10	2	0			

Summary of Discordant Results – Urine Cup:

Sample	Dug Test	Results Recorded	GC/MS Value (ng/mL)
844591	AMP 1000	Positive	952
545390	AMP 1000	Negative	1030
960940	MET 1000	Positive	982
860829	MET 1000	Negative	1054
610670	MET 1000	Negative	1060
572595	MOP 300	Positive	284
898906	MOP 300	Positive	286
710595	COC 300	Negative	322
491069	COC 300	Negative	330
494372	THC 50	Negative	54.3
801073	THC 50	Negative	55.0

b. Matrix comparison:

Not applicable. This device is for use with urine samples only.

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):

The sponsor conducted a study with 300 untrained lay users. A total of 175 males and 125 females from ages of 18 to 47 with a variety of educational background participated in the study at 3 sites. The blind-labeled urine samples were spiked to the following concentrations with 2-5 drugs: negative; 50%, 75%, 125%, 150%, and 200%.

Each lay-user received one test card and one urine cup to test. For each device format (card and cup), a lay-user received a package insert, one blind labeled aliquot, and one device. Each blind-labeled urine sample was tested only once with each device

format. All samples were verified by GC/MS, and the results of lay-user were compared to those of GC/MS. The results are summarized below:

Summary of Lay-user Results – Test Card

Drug	Results	Drug Concentration						Agreement with GC/MS
		Negative	-50%	-25%	+25%	+50%	+100%	
AMP	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
MET	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
MOP	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
COC	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
THC	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	

Summary of Lay-user Results – Urine Cup

Drug	Results	Drug Concentration						Agreement with GC/MS
		Negative	-50%	-25%	+25%	+50%	+100%	
AMP	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
MET	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
MOP	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
COC	+	0	0	0	20	40	20	100%
	-	180	20	20	0	0	0	
THC	+	0	0	0	19	40	20	99.7%
	-	180	20	20	1	0	0	

Each lay-user was also given an English language questionnaire to assess the readability of the labeling and 100% of users indicated that the device instructions can be easily followed.

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.