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

A. 510(k) Number:
k043507

B. Purpose of the Submission:
New 510(k)

C. Analyte:
Oxycodone

D. Type of Test:
Qualitative immunoassay

E. Applicant:
ACON Laboratories, Inc.

F. Proprietary and Established Names:
ACON OXY II One Step Oxycodone Test Strip
ACON OXY II One Step Oxycodone Test Device

G. Regulatory Information:
1. Regulation section:
   862.3650, Enzyme Immunoassay, Opiates
2. Classification:
   Class II
3. Product Code:
   DJG
4. Panel:
   Toxicology (91)

H. Intended Use:
1. Intended use(s):
   Refer to Indications for use.
2. Indication(s) for use:
   The ACON® OXY II One Step Oxycodone Test Strip and the ACON® OXY II One Step Oxycodone Test Device are rapid chromatographic immunoassays for the qualitative detection of oxycodone in urine at a designed cut-off concentration of 100 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

   This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed

analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

3. Special condition for use statement(s):
   The assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/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 used.
   The assay was evaluated in point-of-care settings.
4. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

I. Device Description:

The ACON® OXY II One Step Oxycodone Test Strip and the ACON® OXY II One Step Oxycodone Test Device are immunoassays based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. Oxycodone, if present in the urine specimen below 100 ng/mL, will not saturate the binding sites of antibody in the test device. The antibody coated particles will then be captured by immobilized Oxycodone conjugate and a visible colored line will appear in the test line region. The colored line will not form in the test line region if the Oxycodone level exceeds 100 ng/mL because it will saturate all the binding sites of anti-Oxycodone antibody.
A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region.
To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ACON® OXY One Step Oxycodone Test Strip
   ACON® OXY One Step Oxycodone Test Device
2. Predicate K number(s):
   K033047
3. Comparison with predicate:

The devices and their predicates are for the qualitative determination of the same analyte in the same matrix, and utilize the same cutoff concentrations. All are visually-read single use devices. The major difference is that the new devices, ACON OXY II One Step Oxycodone Test Strip and ACON OXY II One Step Oxycodone Test Device, use a new antibody-antigen system.

K. Standard/Guidance Document Referenced (if applicable):
The sponsor did not identify any in the submission

L. Test Principle:
Lateral flow immunoassay

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

OXY II One Step Oxycodone Test Device

A study was conducted at three independent physician's office sites by three independent, untrained, healthcare professionals using three different lots of product and run in three consecutive days to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded specimens containing no oxycodone, oxycodone spiked at levels +/- 25% of the assay cut-off and oxycodone spiked at levels +/-50% of the 100 ng/mL assay cut-off were provided to each site. The results are given below:

Oxycodone concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

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		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
75	15	14	1	13	2	11	4
125	15	1	14	0	15	0	15
150	15	0	15	0	15	0	15

b. Linearity/assay reportable range:
Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):
Procedural controls are included in the test strip and device. A red line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with these kits; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow local, state, and federal guidelines for testing QC materials.

d. Cutoff Studies:
<u>OXY II One Step Oxycodone Test Device</u>

A drug-free urine pool was spiked with Oxycodone at the following concentrations: 0 ng/mL, 50 ng/mL, 75 ng/mL, 100 ng/mL, 125 ng/mL, 150 ng/mL and 200 ng/mL. The result demonstrates 100% accuracy at 50% above and 25% below the cut-off concentration. The data are summarized below:

Oxycodone Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
75	-25%	30	30	0
100	Cutoff	30	21	9
125	+25%	30	6	24
150	+50%	30	0	30
200	+100%	30	0	30

OXY II One Step Oxycodone Test Strip

A drug-free urine pool was spiked with oxycodone at the following concentrations: 0 ng/mL, 50 ng/mL, 75 ng/mL, 100 ng/mL, 125 ng/mL, 150 ng/mL and 200 ng/mL. The result demonstrates 100% accuracy at 50% above and 25% below the cut-off concentration of the assay. The data are summarized below:

Oxycodone Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
50	-50%	30	30	0
75	-25%	30	30	0
100	Cutoff	30	18	12
125	+25%	30	6	24
150	+50%	30	0	30
200	+100%	30	0	30

e. Analytical specificity:

The following table lists compounds that are positively detected in urine by the OXY II One Step Oxycodone Test Device at 5 minutes.

Compound	Concentration (ng/mL)
Oxycodone	100
Oxymorphone	200
Hydrocodone	6,250
Naloxone	37,500
Naltrexone	37,500
Levorphanol	50,000
Hydromorphone	50,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 50 ng/mL and 150 ng/mL of Oxycodone respectively. The OXY II One Step Oxycodone Test Device was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of Urinary pH

The pH of an aliquot negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with Benzoylecgonine to 50 ng/mL and 150 ng/mL. The spiked, pH-adjusted urine was tested with the OXY II One Step Oxycodone Test Device in duplicate and interpreted according to the package insert. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-negative urine or Oxycodone positive urine. The following compounds show no interference when tested with the OXY II One Step Oxycodone Test Device at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetaminophenol	Acetone	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid	Albumin
6-Acetylcodeine	Amikacin	Albuterol
Amantadine	Amoxapine	Amitriptyline
Amobarbital	Ampicillin	Amoxicillin
d/l-Amphetamine	Apomorphine	Ascorbic acid
Aminopyrine	Atropine	Aspartame
Atenolol	Benzoic acid	Baclofen
Benzilic acid	Bilirubin	Benzoylecgonine
Benzphetamine	Buspirone	Brompheniramine
Buprenorphine	Cannabinol	Caffeine
Cannabidiol	Cimetidine	Carisoprodol
Cephalexin	Chlordiazepoxide	Chloral hydrate
Chloramphenicol	(+) – Chlorpheniramine	Chloroquine
Chlorothiazide	Chlorprothixene	(+/-) - Chlorpheniramine
Chlorpromazine	Clindamycin	Cholorpropamide
Cholesterol	Clozapine	Clomipramine
Clonidine	Cortisone	Cocaine
Codeine	Cyclobarbital	(-) Cotinine
Creatinine	(-)Deoxyephedrine	Cyclobenzaprine
Deoxycorticosterone	Dextromethorphan	R (-) Deprenyl
Dexamethasone	Diflunisal	Diazepam
Dicumarol	Dihydrocodeine	Diclofenac
Digoxin	4-Dimethylaminoantipyrine	Digitoxin
Dicyclomine	(+)-cis-Diltiazem	Diphenhydramine
5,5 –Diphenylhydantoin	Disopyramide	Dimenhydrinate
Droperidol	Ecgonine	Doxylamine
EDDP	EMDP	Ecgonine Methylester
l-Ephedrine	Efavirenz	Emetine dihydrochloride
l-Epinephrine	(-) -Ψ -Ephedrine	Ephedrine
β-Estradiol	(+/-) – Epinephrine	[1R,2S] (-) Ephedrine
Ethyl-p-aminobenzoate	Estrone-3-sulfate	Erythromycin
Fenfluramine	Etodolac	Ethanol
Fluoxetine	Fenoprofen	Ethylmorphine
Gentisic acid	Furosemide	Famprofazone
Fentanyl	d-Glucose	Gentamicin
Hydralazine	Haloperidol	Guaiacol Glyceryl Ether
Hydrocortisone	Hydrochlorothiazide	Hemoglobin
p-Hydroxyamphetamine	p-Hydroxymethamphetamine	o-Hydroxyhippuric acid
Hydroxyzine	p-Hydroxynorephedrine	3-Hydroxytyramine (Dopamine)
Indomethacin	Ibuprofen	Imipramine
(-) Isoproterenol	Insulin	Iproniazide
Ketamine	Isoxsuprine	Kanamycin
Lithium Carbonate	Ketoprofen	Labetalol
Meperidine	Lidocaine	Lindane
Methaqualone	Loperamide	Maprotiline
Methoxyphenamine	Meprobamate	d/l-Methamphetamine
Methylphenidate	l-Methamphetamine	Metoclopramide
Morphine-3-β-D glucuronide	Methadone	MDMA**
Metronidazole	MDA*	Metoprolol
Nalidixic acid	Mephentermine	Methyprylon
α-Naphthaleneacetic acid	Morphine Sulfate	6-Monoacetylmorphine
Nifedipine	Naproxen	Nalorphine.
Nimesulide	Norcodeine	Niacinamide
Norfluoxetine	Norethindrone	Niacinamide
Orphenadrine	Noscapine	Normorphine
Oxalic acid	d-Norpropoxyphene	d/l-Octopamine
Papaverine	Oxymetazoline	Oxolinic Acid
Pentazocine	Pemoline	Oxazepam
Phencyclidine	Pentobarbital	Penicillin-G

Phenobarbital	Phenelzine	Perphenazine
l-Phenylephrine	Phenothiazine	Pheniramine
Prednisolone	β-Phenylethylamine	Phentermine
Procyclidine	Prednisone	(+/-) Phenylpropanolamine
d-Propoxyphene	Promazine	Procaine
d-Pseudoephedrine	d/l-Propranolol	Promethazine
Quinine	Quinacrine	Protriptyline
Salbutamol	Ranitidine	Quinidine
Serotonin	Salicylic acid	Riboflavin
Sulfamethazine	Sulfisoxazole	Secobarbital
Sulfamethoxazole	Sulindac	Spironolactone
Sodium chloride	Tetrahydrozoline	Temazepam
Tetracycline	Thiamine	Tetrahydrocortexolone
Tetrahydrocortisone,3-acetate	l-Thyroxine	Thebaine
Theophylline	Cis-Tramadol	Thioridazine
Thiothixene	Trimethobenzamide	Tobramycin
Tolbutamide	Trifluoperazine	Trans-2-phenylcyclopropylamine
Trazodone	d/l-Tryptophan	Triamterene
Trimipramine	Tyramine	Trimethoprim
Tryptamine	Vancomycin	Vancomycin
d/l-Tyrosine	Uric Acid	Zopiclone
Verapamil	Zomepirac	

*MDA: 3,4-Methylenedioxyamphetamine
**MDMA: 3,4-Methylenedioxymethamphetamine

f. Assay cut-off:

The ACON® OXYII One Step Oxycodone Test Strip/ ACON® OXYII One Step Oxycodone Test Device yields a positive result when the oxycodone level in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cutoff for oxycodone positive specimens.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the detection limit section, above.

2. Comparison studies:

a. Method comparison with predicate device:

OXY II One Step Oxycodone Test Device

300 urine samples were obtained and tested with the OXYCODONE II One Step Oxycodone II Test Device and by GC/MS the results are summarized below:

Specimen Cutoff Range by GC/MS							
		Negative*	< -25% cutoff	-25% to cutoff	Cutoff to +25%	>+25% cutoff	% Agreement
ACON OXY II Test Device	Positive	0	0	1	2	133	99% (135/136)
	Negative	147	6	8	0	3	98% (161/164) (95%-99%)**

Total agreement with GC/MS: 296/300=99% (97%-99%)**

**Denotes 95% confidence interval
*Negative specimens were confirmed using GC/MS analysis by pooling these samples in groups of 5.

OXY II One Step Oxycodone Test Strip

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Specimen Cutoff Range by GC/MS							
		Negative*	< -25% cutoff	-25% to cutoff	Cutoff to +25%	>+25% cutoff	% Agreement
ACON OXY II Test Strip	Positive	0	0	1	2	133	99% (135/136)
	Negative	147	6	8	0	3	98% (161/164) (95%-99%)**

Total agreement with GC/MS: 296/300=99% (97%-99%)**
**Denotes 95% confidence interval
*Negative specimens were confirmed using GC/MS analysis by pooling these samples in groups of 5.

b. Matrix comparison:
Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   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. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.