

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

A. 510(k) Number:

k143187

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine and oxycodone

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Healgen Scientific, LLC.

F. Proprietary and Established Names:

Healgen Amphetamine Test

Healgen Oxycodone Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DKZ	Class II	21 CFR 862.3100, Amphetamine test system	Toxicology (91)
DJG	Class II	21 CFR 862.3650, Opiate test system	Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to Indications for Use below.

2. Indication(s) for use:

Healgen Amphetamine Test

Healgen Amphetamine Test is an immunochromatographic assay for the qualitative determination of Amphetamine in human urine at a Cut-Off concentration of 1000 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Healgen Oxycodone Test

Healgen Oxycodone Test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a Cut-Off concentration of 100 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when prescription drug Oxycodone is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

3. Special conditions for use statement(s):

For over the counter (OTC) and prescription use

4. Special instrument requirements:

Not applicable. The devices are visually read single-use devices.

I. Device Description:

The Healgen Amphetamine Test and Healgen Oxycodone Test come in four formats: Strip, Cassette, Cup, and Dip Card. The Healgen tests use a lateral flow system for the qualitative detection of Amphetamine and Oxycodone in human urine. The tests are intended for 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 in a urine sample. Information regarding confirmatory testing – the second step in the process is provided in the instructions for use.

J. Substantial Equivalence Information:

1. Predicate device name(s):

First Check Multi Drug Cup 12

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

k052115

3. Comparison with predicate:

Similarities and Differences			
Item	Healgen Amphetamine Test (Candidate Device)	Healgen Oxycodone Test (Candidate Device)	k052115
Indications for Use	For the qualitative determination of amphetamine	For the qualitative determination of oxycodone	For the qualitative determination of 12 drugs including amphetamine and oxycodone
Principle	Same	Same	Immunochromatographic lateral flow assay
Cutoff Concentration	Same	Same	AMP: 1000 ng/mL OXY: 100 ng/mL
Intended Use Population	For over-the-counter and prescription use	For over-the-counter and prescription use	For over-the-counter use
Configuration	Strip, Cassette, Dip Card, Cup	Strip, Cassette, Dip Card, Cup	Cup
Type of Test	Same	Same	Qualitative
Specimen Type	Same	Same	Urine

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

None referenced.

L. Test Principle:

The Healgen Amphetamine and Oxycodone Urine Tests use a lateral flow system for the qualitative detection of Amphetamine and Oxycodone in human urine. Each assay uses a monoclonal anti-mouse antibody-dye conjugate against the drugs containing gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in the test membranes.

When the absorbent end of the tests are immersed into the urine specimen, the urine is absorbed into the devices by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target Cut-Off, antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the devices. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target Cut-Off, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the devices. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the tests have been performed properly because of the antibody-dye conjugate binding to anti-mouse IgG immobilized in the Control Region(C) of the devices.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision performance of the Healgen Amphetamine and Oxycodone tests was evaluated using 3 lots for each format (Strip, Cassette, Cup, Dip Card) of the device. Each lot was evaluated by a different operator. The testing consisted of analyzing samples in 2 runs per day for 25 days (n = 50 per lot) and by spiking drug free urine samples to achieve 100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off drug concentrations. Each drug concentration was confirmed by GC/MS. Results are summarized below for each lot and device.

Strip Format

Drug Test	Cut off Level	N	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	18/32	18/32	18/32
	+25%	50	0/50	0/50	0/50
	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
	+100%	50	0/50	0/50	0/50
Oxycodone	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	20/30	20/30	20/30
	+25%	50	0/50	0/50	0/50
	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
	+100%	50	0/50	0/50	0/50

Cassette Format

Drug Test	Cut off Level	N	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	20/30	20/30	20/30
	+25%	50	0/50	0/50	0/50
	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
	+100%	50	0/50	0/50	0/50
Oxycodone	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	20/30	20/30	20/30
	+25%	50	0/50	0/50	0/50

	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
	+100%	50	0/50	0/50	0/50

DipCard Format

Drug Test	Cut off Level	N	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	20/30	20/30	20/30
	+25%	50	0/50	0/50	0/50
	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
+100%	50	0/50	0/50	0/50	

Oxycodone	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	24/26	24/26	24/26
	+25%	50	0/50	0/50	0/50
	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
+100%	50	0/50	0/50	0/50	

Cup Format

Drug Test	Cut off Level	N	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	18/32	18/32	18/32
	+25%	50	0/50	0/50	0/50
	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
+100%	50	0/50	0/50	0/50	
Oxycodone	Negative	50	50/0	50/0	50/0
	-75%	50	50/0	50/0	50/0
	-50%	50	50/0	50/0	50/0
	-25%	50	50/0	50/0	50/0
	Cut-off	50	16/34	16/34	16/34
+25%	50	0/50	0/50	0/50	

	+50%	50	0/50	0/50	0/50
	+75%	50	0/50	0/50	0/50
	+100%	50	0/50	0/50	0/50

b. *Linearity/assay reportable range:*

Not applicable.

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

External control materials are not supplied with the devices; however, the package inserts provides information on how to obtain control materials.

Stability protocols and acceptance criteria of all test formats were reviewed and deemed acceptable. The stability information supports the claimed shelf life of 24 months at 4 to 30 °C. The information also supports that the devices are stable for 35 days when exposed to extreme transport temperatures of -20 °C to 40 °C.

d. *Detection limit:*

Not applicable. The assays are intended for qualitative use.

e. *Analytical specificity:*

Cross-reactivity was evaluated by spiking various concentrations of similarly structured drug compounds into drug-free urine using three lots of each device for all formats. 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:

Amphetamine

Compound	Concentration Equivalent to the Cutoff	Cross-Reactivity
D-Amphetamine	1000 ng/mL	100%
Amphetamine Sulfate	1000 ng/mL	100%
Phentermine	1250 ng/mL	80%
(+/-)-4-Hydroxyamphetamine HCL	600 ng/mL	167%
L-Amphetamine	20,000 ng/mL	5%

(+/-)-Methylene dioxymphetamine (MDA)	1500 ng/mL	67%
D,L-Amphetamine (Amphetamine Sulfate)	1000 ng/mL	100%
d-Methamphetamine	> 100,000 ng/mL	< 1%
l-Methamphetamine	> 100,000 ng/mL	< 1%
ephedrine	> 100,000 ng/mL	< 1%
3,4-Methylenedioxy ethylamphetamine (MDEA)	> 100,000 ng/mL	< 1%
3,4-methylenedioxy-methamphetamine (MDMA)	> 100,000 ng/mL	< 1%

Oxycodone

Compound	Concentration Equivalent to the Cutoff	Cross-Reactivity
Oxycodone	100 ng/mL	100%
Oxymorphone	750 ng/mL	13%
Dihydrocodeine	12,500 ng/mL	0.8%
Codeine	50,000 ng/mL	0.2%
Thebaine	50,000 ng/mL	0.2%
Ethyl Morphine	75,000 ng/mL	0.1%
Morphine	>100,000 ng/mL	< 0.1%
Acetylmorphine	>100,000 ng/mL	< 0.1%
Buprenorphine	>100,000 ng/mL	< 0.1%
Ethylmorphine	>100,000 ng/mL	< 0.1%
Hydromorphone	>100,000 ng/mL	< 0.1%
Hydrocodone	>100,000 ng/mL	< 0.1%

Interference studies were performed using 100 µg/mL of commonly administered or OTC compounds (endogenous compounds, drugs, drug metabolites) that are

commonly found in urine. These compounds were tested in urine containing $\pm 25\%$ cutoff concentration for each analyte using three lots of each device for all formats. The following compounds were found not to interfere when tested at 100 $\mu\text{g/mL}$ concentration.

Amphetamine

Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic Acid (Aspirin)
Aminopyrine
Amitriptyline
Amoxicillin
Amobarbital
Ampicillin
Apomorphine
L-Ascorbic Acid
Aspartame
Atropine
Benzilic acid
Benzphetamine
Bezoic Acid
Bilirubin
Caffeine
Chloramphenicol
Chlordiazepoxide HCL
Chloroquine
Chlorothiazide
Chlorpheniramine
Chlorpromazine
Cholesterol
Clomipramine
Clonidine hydrochloride
Codeine
Cortisone
Cotinine(-)
Creatinine
Deoxyepinephrine
Dextromethorphan

Diazepam
Diflunisal
Digoxin
Doxylamine
Ecgonine methylester
R(-)-Epinephrine
Erythromycin
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenopropfen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
a -Hydroxyhippuric acid
p- Hydroxymethamphetamine
Ibuprofen
Imipramine
Isoxsuprine
Isoproterenol-(+/-)
Ketamine
Labetalol
Levorphanol
Loperamide
Maprotiline
Meprobamate
Methadone
Methoxyphenamine
Methylphenidate

Nalbuphine
Nalidixic acid
Naloxone hydrochloride
Naltrexone hydrochloride
Naproxen
Niacinamide
Nifedipine
Norethindrone
Norpropoxyphene
Noscapine
Oxazepam
Oxycodone
Oxymetazoline
Papaverine
Penicillin
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phenylephrine-L
Phenylethylamine
Phenylpropanolamine
Prednisolone Acetate
Prednisone
Procaine (Novocaine)
Promazine
Promethazine
Propoxyphene,d-
Propranolol
Pseudoephedrine HCL
Quinidine
Quinine

Ranitidine(Zantac)
Salicylic Acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
11-Nor- Δ^9 - Tetrahydrocannabinol
Tetracycline

Tetrahydrozoline
Thebaine
Thiamine
L-Thyroxine
Thioridazine Hydrochloride
Triamterene
Triflupromazine Hydrochloride
Trimethoprim

Trimipramine
Tryptamine
DL-Tryptophan
Tyramine
D/L-Tyrosine
Uric Acid
Verapamil
Zomepirac

Oxycodone

Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic Acid (Aspirin)
Aminopyrine
Amitriptyline
Amoxicillin
Amobarbital
D-Amphetamine
L-Amphetamine
Amphetamine Sulfate
Ampicillin (Ampicillin)
Apomorphine
L-Ascorbic Acid
Aspartame
Atropine
Benzilic acid
Benzphetamine
Bezoic Acid
Bilirubin
Caffeine
Chloramphenicol
Chlordiazepoxide HCL
Chloroquine
Chlorothiazide
Chlorpheniramine

Chlorpromazine
Cholesterol
Clomipramine
Clonidine hydrochloride
Cortisone
Cotinine(-)
Creatinine
Deoxyepinephrine
Dextromethorphan
Diazepam
Diflunisal
Digoxin
Doxylamine
Ecgonine methylester
R(-)-Epinephrine
Erythromycin
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenopropfen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
(+/-)-4- Hydroxyamphetamine HCL
Hydrochlorothiazide

Hydrocodone
Hydrocortisone
a -Hydroxyhippuric acid
p- Hydroxymethamphetamine
Ibuprofen
Imipramine
Isoxsuprine
Isoproterenol-(+/-)
Ketamine
Labetalol
Levorphanol
Loperamide
Maprotiline
Meprobamate
Methadone
Methoxyphenamine
(+/-)-Methylenedioxy amphetamine (MDA)
Methylphenidate
Nalbuphine
Nalidixic acid
Naloxone hydrochloride
Naltrexone hydrochloride
Naproxen
Niacinamide

Nifedipine
Norethindrone
Norpropoxyphene
Noscapine
Oxazepam
Oxymetazoline
Papaverine
Penicillin
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
Phenylephrine-L
Phenylethylamine
Phenylpropanolamine
Prednisolone Acetate

Prednisone
Procaine(Novocaine)
Promazine
Promethazine
Propoxyphene,d-
Propranolol
Pseudoephedrine HCL
Quinidine
Quinine
Ranitidine(Zantac)
Salicylic Acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
11-Nor- Δ 9-Tetrahydrocannabinol

Tetracycline
Tetrahydrozoline
Thiamine
L-Thyroxine
Thioridazine Hydrochloride
Triamterene
Triflupromazine Hydrochloride
Trimethoprim
Trimipramine
Tryptamine
DL-Tryptophan
Tyramine
D/L-Tyrosine
Uric Acid
Verapamil
Zomepirac

Specific Gravity and pH studies:

Twelve urine samples with specific gravity ranges (1.000-1.035) were collected and spiked with each drug at 25% below and 25% above cutoff levels. Each sample was tested using three lots of each format of the test devices. The results showed that a specific gravity range of 1.000 to 1.035 does not affect the accuracy of the tests.

A negative urine pool was adjusted to a pH range of 4.00 to 9.00 in 1 pH unit increments and was spiked with each drug at 25% below and 25% above cutoff levels. Samples were tested using three lots of each format of the devices, and results showed that urine pH range of 4.00 to 9.00 does not affect the accuracy of the accuracy of the tests.

f. Assay cut-off:

The assay cutoff characterization study was performed using the Healgen Amphetamine Test and the Healgen Oxycodone Test with three lots for each format (Cup, Dip Card, Cassette, and Strip format) by three operators. The study samples were made by spiking drug-free urine samples (confirmed by GC/MS) with known amounts of amphetamine or oxycodone. Results are shown in the tables below:

Strip Format

Drug Test	Cut off Level	n	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	42/48	42/48	45/45
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Oxycodone	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	48/42	42/48	42/48
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90

Cassette Format

Drug Test	Cut off Level	n	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	45/45	45/45	42/48
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Oxycodone	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	42/48	45/45	51/39
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90

Dip Card Format

Drug Test	Cut off Level	n	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	42/48	42/48	45/45
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Oxycodone	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	45/45	48/42	42/48
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90

Cup Format

Drug Test	Cut off Level	n	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Amphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	42/48	42/48	42/48
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Oxycodone	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	45/45	42/48	45/45
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90

2. Comparison studies:

a. *Method comparison with predicate device:*

The method comparison for the Healgen Amphetamine Test and the Healgen Oxycodone Test was performed internally against the reference method, GC/MS. Operators ran 80 unaltered urine samples on each format of the devices, where each device format was tested by an independent set of three operators. The samples were masked and randomized prior to testing and device results were compared to GC/MS. The results are presented in the table below:

Amphetamine Strip Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Operator B	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Operator C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

Discordant Results with Amphetamine Strip

Operator	GC/MS result (ng/mL)	Operator result
Operator A	1006	Negative
Operator A	1009	Negative
Operator A	1010	Negative
Operator B	1011	Negative
Operator B	1006	Negative
Operator B	1009	Negative
Operator C	1011	Negative
Operator C	1006	Negative
Operator C	1009	Negative
Operator C	1010	Negative

Amphetamine Cassette Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Operator C	Positive	0	0	0	14	23
	Negative	10	16	14	3	0

Discordant Results with Amphetamine Cassette

Operator	GC/MS result (ng/mL)	Operator result
Operator A	1006	Negative
Operator A	1009	Negative
Operator B	1011	Negative
Operator B	1006	Negative
Operator B	1009	Negative
Operator C	1006	Negative
Operator C	1009	Negative
Operator C	1010	Negative

Amphetamine Cup Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Operator C	Positive	0	0	0	15	23
	Negative	10	16	14	2	0

Discordant Results with Amphetamine Cup

Operator	GC/MS result (ng/mL)	Operator result
Operator A	1006	Negative
Operator A	1010	Negative
Operator B	1011	Negative
Operator B	1006	Negative
Operator B	1009	Negative
Operator B	1015	Negative
Operator C	1006	Negative
Operator C	1010	Negative

Amphetamine Dip Card Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Operator C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

Discordant Results with Amphetamine Dip Card

Operator	GC/MS result (ng/mL)	Operator result
Operator A	1006	Negative
Operator A	1010	Negative
Operator B	1011	Negative
Operator B	1006	Negative
Operator B	1009	Negative
Operator B	1015	Negative
Operator C	1011	Negative
Operator C	1006	Negative
Operator C	1009	Negative
Operator C	1010	Negative

Oxycodone Strip Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results with Oxycodone Strip

Operator	GC/MS result (ng/mL)	Operator result
Operator A	101	Negative
Operator A	103	Negative
Operator A	105	Negative
Operator B	101	Negative
Operator B	105	Negative
Operator C	101	Negative
Operator C	103	Negative
Operator C	105	Negative

Oxycodone Cassette Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results with Oxycodone Cassette

Operator	GC/MS result (ng/mL)	Operator result
Operator A	101	Negative
Operator A	103	Negative
Operator A	105	Negative
Operator B	101	Negative
Operator B	103	Negative
Operator B	105	Negative
Operator C	101	Negative
Operator C	103	Negative
Operator C	105	Negative

Oxycodone Dip Card Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results with Oxycodone Dip Card

Operator	GC/MS result (ng/mL)	Operator result
Operator A	101	Negative
Operator A	103	Negative
Operator A	105	Negative
Operator B	101	Negative
Operator B	105	Negative
Operator C	101	Negative
Operator C	103	Negative
Operator C	105	Negative

Oxycodone Cup Format

Operator		Negative	Low Negative by GC/MS (<-50%)	Near Cutoff Negative by GC/MS (between -50% and	Near Cutoff Positive by GC/MS (between cutoff and	High Positive by GC/MS (> +50%)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results with Oxycodone Cup

Operator	GC/MS result (ng/mL)	Operator result
Operator A	101	Negative
Operator A	103	Negative
Operator A	105	Negative
Operator B	101	Negative
Operator B	103	Negative
Operator B	105	Negative
Operator C	101	Negative
Operator C	103	Negative
Operator C	105	Negative

b. *Matrix comparison:*

Not applicable. The assays are intended to be used 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):*

A lay user study was performed at three sites where 1120 lay persons tested one of

the four formats (Strip, Cassette, Dip Card, Cup) of the Healgen Amphetamine Test and the Healgen Oxycodone Test (140 readers across three sites x 4 formats x 2 analytes = 1120). The participants had diverse educational and professional backgrounds and ranged in age from 21 to 63 years. Urine samples were prepared at the following concentrations; negative, $\pm 75\%$, $\pm 50\%$, $\pm 25\%$ of the cutoff by spiking drug into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled, and randomized prior to testing. Each participant was provided with the package insert, one masked sample and a device. The results are summarized below.

Strip Format

Drug	Cutoff	Conc. by GC/MS (ng/mL)	n	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Amphetamine	-100%	0	20	0	20	100%
	-75%	250	20	0	20	100%
	-50%	500	20	0	20	100%
	-25%	750	20	2	18	90%
	+25%	1250	20	19	1	95%
	+50%	1500	20	20	0	100%
	+75%	1750	20	20	0	100%
Oxycodone	-100%	0	20	0	20	100%
	-75%	25	20	0	20	100%
	-50%	50	20	0	20	100%
	-25%	75	20	2	18	90%
	+25%	125	20	18	2	90%
	+50%	150	20	20	0	100%
	+75%	175	20	20	0	100%

Cassette Format

Drug	Cutoff	Conc. by GC/MS (ng/mL)	n	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Amphetamine	-100%	0	20	0	20	100%
	-75%	250	20	0	20	100%
	-50%	500	20	0	20	100%
	-25%	750	20	1	19	95%
	+25%	1250	20	19	1	95%
	+50%	1500	20	20	0	100%
	+75%	1750	20	20	0	100%

Oxycodone	-100%	0	20	0	20	100%
	-75%	25	20	0	20	100%
	-50%	50	20	0	20	100%
	-25%	75	20	1	19	95%
	+25%	125	20	19	1	95%
	+50%	150	20	20	0	100%
	+75%	175	20	20	0	100%

Cup Format

Drug	Cutoff	Conc. by GC/MS (ng/mL)	n	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Amphetamine	-100%	0	20	0	20	100%
	-75%	250	20	0	20	100%
	-50%	500	20	0	20	100%
	-25%	750	20	1	19	95%
	+25%	1250	20	20	0	100%
	+50%	1500	20	20	0	100%
	+75%	1750	20	20	0	100%
Oxycodone	-100%	0	20	0	20	100%
	-75%	25	20	0	20	100%
	-50%	50	20	0	20	100%
	-25%	75	20	1	19	95%
	+25%	125	20	19	1	95%
	+50%	150	20	20	0	100%
	+75%	175	20	20	0	100%

Dip Card Format

Drug	Cutoff	Conc. by GC/MS (ng/mL)	n	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Amphetamine	-100%	0	20	0	20	100%
	-75%	250	20	0	20	100%
	-50%	500	20	0	20	100%
	-25%	750	20	1	19	95%
	+25%	1250	20	18	2	90%
	+50%	1500	20	20	0	100%
	+75%	1750	20	20	0	100%

Oxycodone	-100%	0	20	0	20	100%
	-75%	25	20	0	20	100%
	-50%	50	20	0	20	100%
	-25%	75	20	2	18	90%
	+25%	125	20	18	2	90%
	+50%	150	20	20	0	100%
	+75%	175	20	20	0	100%

The labeling is rated at 7th grade reading level per Flesch-Kincaid Methodology. All participants (100%) indicated on the questionnaire that the labeling instructions were clear or very clear and that they did not find the tests difficult to operate.

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.