

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

A. 510(k) Number:

k140546

B. Purpose for Submission:

New Device

C. Measurand:

Marijuana (THC) and Methamphetamine (MET)

D. Type of Test:

Qualitative lateral flow chromatographic competitive binding immunoassay

E. Applicant:

Healgen Scientific LLC.

F. Proprietary and Established Names:

Healgen THC One Step Marijuana Test
Healgen mAMP One Step Methamphetamine Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LDJ	II	21 CFR §862.3870 Cannabinoid Test System	Toxicology (91)
LAF	II	21 CFR §862.3610 Methamphetamine Test System	Toxicology (91)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

Healgen THC One Step Marijuana Test

Healgen One Step Marijuana Test is an immunochromatographic assay for the qualitative determination of 11-nor- Δ^9 -THC-9-COOH in human urine at a cut-off concentration of 50 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 mAMP One Step Methamphetamine Test

Healgen One Step Methamphetamine Test is an immunochromatographic assay for the qualitative determination of methamphetamine 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.

3. Special conditions for use statement(s):

For over the counter (OTC) and prescription use

4. Special instrument requirements:

Not applicable. The device is a visually read single-use device.

I. Device Description:

The Healgen THC One Step Marijuana Test and Healgen mAMP One Step Methamphetamine Test come in four formats: Strip, Cassette, Cup, and Dip Card. The Healgen tests use a lateral flow, one step system for the qualitative detection of 11-nor- Δ^9 -THC-9-COOH and Methamphetamine in human urine.

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 THC One-Step Marijuana Test (Candidate Device)	Healgen mAMP One-Step Methamphetamine Test (Candidate Device)	First Check Multi Drug Cup 12 (Predicate Device)
Indications for Use	For the qualitative determination of 11-nor- Δ^9 -THC-9-COOH	For the qualitative determination of methamphetamine	Same except this device detects a total of 12 drugs
Principle	Immunochromatographic lateral flow assay	Immunochromatographic lateral flow assay	Same
Cutoff Concentration	50 ng/mL	1000 ng/ mL	Same
Intended Use	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	Qualitative to indicate positive or negative result	Qualitative to indicate positive or negative result	Same
Specimen Type	Human urine	Human urine	Same

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

None referenced.

L. Test Principle:

The devices are rapid tests for the qualitative detection of marijuana and methamphetamine in urine samples. When the absorbent end of the device is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentrations below the

target cut off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When the analyte concentration is above the cutoff, analyte molecules bind 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 device. When the sample contains target drug above the cutoff concentration no colored band shows in the test region, indicating a preliminary positive result. A control line (C line) is also part of each device. The C line is coated with anti-mouse IgG polyclonal antibody and serves as an internal quality control of the system. The C line appears as a red-colored band during the test regardless of the presence of the drug.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision of the Healgen THC One step Marijuana and Healgen mAMP One Step Methamphetamine tests were tested with 3 lots for each format (Strip, Cassette, Cup, Dip Card) of the device by three operators. This 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
Marijuana (THC)	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	12/38	12/38	12/38
	+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
Methamphetamine	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	14/36	14/36	14/36
	+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
Marijuana (THC)	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
Methamphetamine	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

Cup Format

Drug Test	Cut off Level	N	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Marijuana (THC)	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	14/36	14/36	14/36
	+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
Methamphetamine	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	22/28	22/28	22/28
	+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
Marijuana (THC)	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
Methamphetamine	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

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 insert lists a phone number the users can call to determine the commercial controls that are compatible for use with this device.

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 and 40 °C.

d. *Detection limit:*

Not applicable. The assay is intended for qualitative use.

e. *Analytical specificity:*

Cross-reactivity was evaluated by spiking various concentrations of similarly structured drug 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 presented below:

Marijuana (THC)

Compound	Concentration Equivalent to the Cutoff	% Cross-Reactivity
THC (11 -nor - Δ 9 -THC THC-9-COOH Cutoff =50ng/mL	50 ng/mL	100%
Delta -9-Tetrahydrocannabinol	50,000 ng/mL	0.1%
11-nor-delta-9-THC-carboxylglucuronide	75 ng/mL	67%
(-)-11-nor-9-carboxy-delta9-THC	50 ng/mL	67%
11-Nor- Δ 9-Tetrahydrocannabinol	50 ng/mL	100%
11-Hydroxy- Δ 9-Tetrahydrocannabinol	5,000 ng/mL	1%
11-Nor- Δ 8-Tetrahydrocannabinol	50 ng/mL	100%
Δ 8-THC-COOH	50,000 ng/mL	0.1%

Methamphetamine (MET)

Compound	Concentration Equivalent to the Cutoff	% Cross-Reactivity
D- Methamphetamine Cutoff = 100ng/mL	1000 ng/mL	100%
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000 ng/mL	5%
Procaine (Novocaine)	60,000 ng/mL	1.7%
Trimethobenzamide	20,000 ng/mL	5%
Methamphetamine	1000 ng/mL	100%
Ranitidine (Zantac)	50,000 ng/mL	2%
(+/-) 3,4-Methylenedioxymethamphetamine	2500 ng/mL	40%
Chloroquine	50,000 ng/mL	2%
Ephedrine	100,000 ng/mL	1%
Fenfluramine	50,000 ng/mL	2%
p-Hydroxymethamphetamine	10,000 ng/mL	10%

Interference studies:

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 drug-free urine controls and urine containing ±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 µg/mL concentration.

THC

4-Acetamidophenol	Estrone-3-sulfate	Penicillin-G
Acetophenetidin	Ethyl-p-aminobenzoate	Pentazocine
N-Acetylprocainamide	Fenoprofen	Pentobarbital
Acetylsalicylic acid	Furosemide	Perphenazine
Aminopyrine	Gentisic acid	Phencyclidine
Amitriptyline	Hemoglobin	Phenelzine
Amobarbital	Hydralazine	Phenobarbital
Amoxicillin	Hydrochlorothiazide	Phentermine
Ampicillin	Hydrocodone	L-Phenylephrine
Ascorbic acid	Hydrocortisone	β-Phenylethylamine
D,L-Amphetamine	O-Hydroxyhippuric acid	β-Phenyllethylamine
L-Amphetamine	3-Hydroxytyramine	Phenylpropanolamine
Apomorphine	Ibuprofen	Prednisolone
Aspartame	Imipramine	Prednisone
Atropine	Iproniazid	Procaine
Benzilic acid	(-) Isoproterenol	Promazine
Benzoic acid	Isoxsuprine	Promethazine
Benzoyllecgonine	Ketamine	D,L-Propranolol
Benzphetamine	Ketoprofen	D-Propoxyphene
Bilirubin	Labetalol	D-Pseudoephedrine
Brompheniramine	Levorphanol	Quinidine
Caffeine	Loperamide	Quinine
Chloralhydrate	Maprotiline	Ranitidine
Chloramphenicol	Meprobamate	Salicylic acid
Chlordiazepoxide	Methadone	Secobarbital
Chlorothiazide	Methoxyphenamine	Serotonin (5-
(±) Chlorpheniramine	(+) 3,4-Methylenedioxyamphetamine	Sulfamethazine
Chlorpromazine	(+)3,4-Methylenedioxymethampheta	Sulindac
Chlorquine	Methylphenidate	Temazepam
Cholesterol	Methypylon	Tetracycline
Clomipramine	Morphine-3-β-Dglucuronide	Tetrahydrocortisone, 3 Acetate

Clonidine	Nalorphine	Tetrahydrocortisone3 (5-Dglucuronide)
Cocaine hydrochloride	Naloxone	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naltrexone	Thiamine
(-) Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamine
Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diflunisal	Noscapine	Trimipramine
Digoxin	D,L-Octopamine	Tryptamine
Diphenhydramine	Oxalic acid	D, L-Tryptophan
Doxylamine	Oxazepam	Tyramine
Ecgonine hydrochloride	Oxolinic acid	PrD, L-Tyrosine
Ecgonine methylester	Oxycodone	Uric acid
(-) Y Ephedrine	Oxymetazoline	Verapamil
Erythromycin	p-Hydroxymethamphetamine	Zomepirac
β-Estradiol	Papaverine	

MET

4-Acetamidophenol	(-) Y Ephedrine	Penicillin-G
Acetophenetidin	Erythromycin	Pentazocaine
N-Acetylprocainamide	β-Estradiol	Pentobarbital
Acetylsalicylic acid	Estrone-3-sulfate	Perphenazine
Aminopyrine	Ethyl-p-aminobenzoate	Phencyclidine
Amitriptyline	Fenfluramine	Phenelzine
Amobarbital	Fenoprofen	Phendimetrazine
Amoxicillin	Furosemide	Phenobarbital
Ampicillin	Gentisic acid	Phetoin
Ascorbic acid	Hemoglobin	L-Phenylephrine
Apomorphine	Hydralazine	β-Phenylethlamine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Atropine	Hydrocodone	Prednisolone

Benzilic acid	Hydrocortisone	Prednisone
Benzoic acid	O-Hydroxyhippuric acid	Procaine
Benzoylecgonine	3-Hydroxytyramine	Promazine
Bilirubin	Ibuprofen	Promethazine
Brompheniramine	Imipramine	D,L-Propranolol
Caffeine	(-) Isoproterenol	Propiomazine
Cannabidiol	Isoxsuprine	D-Propoxyphene
Cannabinol	Ketamine	Quinidine
Chloralhydrate	Ketoprofen	Quinine
Chloramphenicol	Labetalol	Ranitidine
Chlordiazepoxide	Levorphanol	Salicylic acid
Chlorothiazide	Loperamide	Secobarbital
(±) Chlorpheniramine	Maprotiline	Serotonin
Chlorpromazine	Meperidine	Sulfamethazine
Chlorquine	Meprobamate	Sulindac
Cholesterol	Methadone	Temazepam
Clomipramine	Methylphenidate	Tetracycline
Clonidine	Morphine-3-Dglucuronide	Tetrahydrocortisone
Cocaine hydrochloride	Nalidixic acid	Tetrahydrozoline
Codeine	Naloxone	Δ9-THC-COOH
Cortisone	Naltrexone	Thebaine
(-) Cotinine	Naproxen	Thiamine
Creatinine	Niacinamide	Thioridazine
Deoxycorticosterone	Nifedipine	D,L-Thyroxine
Dextromethorphan	Norcodein	Tolbutamine
Diazepam	Norethindrone	Triamterene
Diclofenac	D-Norpropoxyphene	Trifluoperazine
Diflunisal	Noscapine	Trimethoprim
Digoxin	D,L-Octopamine	Trimipramine
Diphenhydramine	Oxalic acid	Tryptamine
Doxylamine	Oxazepam	D, L-Tyrosine
Ecgonine hydrochloride	Oxolinic acid	Uric acid
Ecgonine methylester	Oxycodone	Verapamil
(1R,2S)-(-)-Ephedrine	Oxymetazoline	Zomepirac
L-Ephedrine	Papaverine	Acebutolol

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 test

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 test.

f. Assay cut-off:

The assay cutoff characterization study was performed using the Healgen THC One Step Marijuana Test and the Healgen mAMP One Step Methamphetamine Test with 3 lots for each format (Cup, Dip Card, Cassette, and Strip format) by three operators. The study samples were made by using spiking drug-free urine samples (confirmed by GC/MS) with known amount of THC or Methamphetamine. Results are shown in the tables below:

Strip Format

Drug Test	Cut off Level	N	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Marijuana (THC)	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	30/60	27/63	18/72
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Methamphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	24/66	30/60	36/54
	+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
Marijuana (THC)	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	36/54	45/45	30/60
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Methamphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	39/51	48/42	51/39
	+25%	30	0/90	0/90	0/90

	+50%	30	0/90	0/90	0/90
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Dip Card Format

Drug Test	Cut off Level	N	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
Marijuana (THC)	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	42/48	36/54	48/42
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Methamphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	36/54	48/42	39/51
	+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
Marijuana (THC)	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	49/51	48/42	51/39
	+25%	30	0/90	0/90	0/90
	+50%	30	0/90	0/90	0/90
Methamphetamine	-50%	30	90/0	90/0	90/0
	-25%	30	90/0	90/0	90/0
	Cut-off	30	30/60	42/48	30/60
	+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 THC One Step Marijuana Test and the Healgen mAMP One Step Methamphetamine 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:

THC 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	26
	Negative	10	16	16	1	0
Operator B	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Operator C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

Discordant Result of THC Strip

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	223	52	Negative
Operator B	207	53	Negative
Operator B	223	52	Negative
Operator C	207	53	Negative
Operator C	223	52	Negative

THC 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	12	26
	Negative	10	16	16	2	0
Operator B	Positive	0	0	0	11	26
	Negative	10	16	16	3	0
Operator C	Positive	0	0	0	11	26
	Negative	10	16	16	3	0

Discordant Result of THC Cassette

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	223	52	Negative
Operator A	247	53	Negative
Operator B	207	53	Negative
Operator B	247	53	Negative
Operator B	223	52	Negative
Operator C	207	53	Negative
Operator C	247	53	Negative
Operator C	223	52	Negative

THC 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	12	26
	Negative	10	16	16	2	0
Operator B	Positive	0	0	0	11	26
	Negative	10	16	16	3	0
Operator C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

Discordant Result of THC Cup

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	223	52	Negative
Operator A	247	53	Negative
Operator B	207	53	Negative
Operator B	247	53	Negative
Operator B	223	52	Negative
Operator C	207	53	Negative
Operator C	247	53	Negative

THC 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	26
	Negative	10	16	16	1	0
Operator B	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Operator C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

Discordant Result of THC Dip Card

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	223	52	Negative
Operator B	207	53	Negative
Operator B	223	52	Negative
Operator C	207	53	Negative
Operator C	247	53	Negative

MET 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	12	27
	Negative	10	19	15	1	0
Operator B	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Operator C	Positive	0	0	0	12	27
	Negative	10	19	15	1	0

Discordant Result of MET Strip

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	133	1008	Negative
Operator B	123	1003	Negative
Operator B	133	1008	Negative
Operator C	133	1008	Negative

MET 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	11	27
	Negative	10	19	15	2	0
Operator B	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Operator C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

Discordant Result of MET Cassette

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	123	1003	Negative
Operator A	133	1008	Negative
Operator B	123	1003	Negative
Operator C	123	1003	Negative
Operator C	133	1008	Negative

MET 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	11	27
	Negative	10	19	15	2	0
Operator B	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Operator C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

Discordant Result of MET Dip Card

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	123	1003	Negative
Operator A	133	1008	Negative
Operator B	123	1003	Negative
Operator B	133	1008	Negative
Operator C	123	1003	Negative
Operator C	133	1008	Negative

MET 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	12	27
	Negative	10	19	15	1	0
Operator B	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Operator C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

Discordant Result of MET Cup

Operator	Sample Number	GC/MS result (ng/mL)	Operator result
Operator A	123	1003	Negative
Operator B	123	1003	Negative
Operator C	123	1003	Negative
Operator C	133	1008	Negative

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):*

A lay user study was performed at three sites with a total of 560 lay persons where 140 persons tested one of the four formats (Strip, Cassette, Dip Card, Cup) of the Healgen THC One Step Marijuana Test and the Healgen mAMP One Step Methamphetamine Test. The participants had diverse educational and professional backgrounds and ranged in age from 21 to >50. 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)	No. of samples	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Marijuana	-100%	0	20	0	20	100%
	-75%	12.5	20	0	20	100%
	-50%	25	20	0	20	100%
	-25%	37.5	20	1	19	95%
	+25%	62.5	20	19	1	95%
	+50%	75	20	20	0	100%
	+75%	87.5	20	20	0	100%
Methamphetamine	-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%

Cassette Format

Drug	Cutoff	Conc. by GC/MS (ng/mL)	No. of samples	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Marijuana	-100%	0	20	0	20	100%
	-75%	12.5	20	0	20	100%
	-50%	25	20	0	20	100%
	-25%	37.5	20	1	19	95%
	+25%	62.5	20	18	2	90%
	+50%	75	20	20	0	100%
	+75%	87.5	20	20	0	100%
Methamphetamine	-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%

Cup Format

Drug	Cutoff	Conc. by GC/MS (ng/mL)	No. of samples	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Marijuana	-100%	0	20	0	20	100%
	-75%	12.5	20	0	20	100%
	-50%	25	20	0	20	100%
	-25%	37.5	20	3	17	85%
	+25%	62.5	20	20	0	100%
	+50%	75	20	20	0	100%
	+75%	87.5	20	20	0	100%
Methamphetamine	-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	17	3	85%
	+50%	1500	20	20	0	100%
	+75%	1750	20	20	0	100%

Dip Card Format

Drug	Cutoff	Conc. by GC/MS (ng/mL)	No. of samples	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
Marijuana	-100%	0	20	0	20	100%
	-75%	12.5	20	0	20	100%
	-50%	25	20	0	20	100%
	-25%	37.5	20	2	18	90%
	+25%	62.5	20	19	1	95%
	+50%	75	20	20	0	100%
	+75%	87.5	20	20	0	100%
Methamphetamine	-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%

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 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.