K140546

510(k) SUMMARY

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1. Date: May 29, 2014

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4. Device Name: Healgen THC One Step Marijuana Test
Healgen mAMP One Step Methamphetamine Test

Classification:

Product Code	CFR #	Panel
LDJ	21 CFR, 862.3870 Cannabinoid Test System	Toxicology
LAF	21 CFR, 862.3610 Methamphetamine Test System	Toxicology

5. Predicate Devices:
K052115
FIRST CHECK DIAGNOSTICS LLC

6. Intended Use
Healgen THC One Step Marijuana Test is an immunochromatographic assay for the qualitative determination of 11-nor-Δ9-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 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.

7. Device Description

Immunochromatographic assays for Marijuana and Methamphetamine Urine Tests use a lateral flow, one step system for the qualitative detection of 11-nor-Δ9-THC-9-COOH and Methamphetamine (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen THC One Step Marijuana Test and Healgen mAMP One Step Methamphetamine Test and the predicate devices is provided in Table 1 & Table 2.

Table 1: Features Comparison of Healgen THC One Step Marijuana Test and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of 11-nor-Δ9-THC-9-COOH in human urine.	Same (but the number of drugs detected is different)
Calibrator	11-nor-Δ9-THC-9-COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	50 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

Table 2: Features Comparison of Healgen mAMP One Step Methamphetamine Test and the Predicate Devices

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of Methamphetamine in human urine.	Same(but the number of drugs detected is different)
Calibrator	Methamphetamine	Same

Item	Device	Predicate - K052115
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	1000 ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

9. Test Principle

It is a rapid test for the qualitative detection of 11-nor-Δ9-THC-9-COOH and Methamphetamine in urine samples. It is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -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. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled by the person who prepared the samples and won't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following table.

THC Strip Format

Result / Drug	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:THC1110001	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110002	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110003	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-

THC Cassette Format

Drug \ Result	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:THC1110004	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110005	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110006	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

THC Cup Format

Drug \ Result	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:THC1110007	50-/0+	50-/0+	50-/0+	50-/0+	14-/36+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110008	50-/0+	50-/0+	50-/0+	50-/0+	14-/36+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110009	50-/0+	50-/0+	50-/0+	50-/0+	14-/36+	50+/0-	50+/0-	50+/0-	50+/0-

THC Dipcard Format

Drug \ Result	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:THC1110010	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110011	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:THC1110012	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

MET Strip Format

Drug \ Result	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:MET1110001	50-/0+	50-/0+	50-/0+	50-/0+	14-/36+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110002	50-/0+	50-/0+	50-/0+	50-/0+	14-/36+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110003	50-/0+	50-/0+	50-/0+	50-/0+	14-/36+	50+/0-	50+/0-	50+/0-	50+/0-

MET Cassette Format

Drug \ Result	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:MET1110004	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110005	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110006	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

MET Dip Card Format

Drug \ Result	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:MET1110007	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110008	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110009	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

MET CUP Format

Drug \ Result	-100%cut off	-75%cut off	-50%cut off	-25% cutoff	cut off	+25%cut off	+50%cut off	+75%cut off	+100%cut off
Lot:MET1110010	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110011	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MET1110012	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable, this is a visually read device

c. Stability

It is stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C and real time stability determination at both 4 °C and 30 °C.

d. Cut-off

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for both Marijuana and Methamphetamine. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
One Step Marijuana Test	11-nor-Δ9-THC-9-COOH	50
One Step Methamphetamine Test	Methamphetamine	1000

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentration at 25% below and 25% above Cut-Off level respectively. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different formats.

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
Amitryptyline	Hemoglobin	Phenelzine
Amobarbital	Hydralazine	Phenobarbital
Amoxicillin	Hydrochlorothiazide	Phentermine
Ampicillin	Hydrocodone	L-Phenylephrine
Ascorbic acid	Hydrocortisone	β-Phenylethlamine
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
Benzoylecgonine	Ketamine	D,L-Propanolol
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-Hydroxytyramine)
(±) Chlorpheniramine	(+) 3,4-Methylenedioxyamphetamine	Sulfamethazine
Chlorpromazine	(+)3,4-Methylenedioxymethampheta mine	Sulindac
Chlorquine	Methylphenidate	Temazepam
Cholesterol	Methyprylon	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
Amitryptyline	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-Propanolol
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
(IR,2S)-(-)-Ephedrine	Oxymetazoline	Zomepirac
L-Ephedrine	Papaverine	Acebutolol

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for all formats. Compounds that produced positive results are listed below. There were no differences observed for different formats.

THC (11-nor-Δ9-THC-9-COOH, Cutoff=50 ng/mL)	Result Positive at 50 ng/mL	% Cross-Reactivity 100%
Delta-9-Tetrahydrocannabinol	Positive at 50,000 ng/mL	0.1%
11-nor-delta-9-THC-carboxyglucuronide	Positive at 75 ng/mL	67%
(-)-11-nor-9-carboxy-delta9-THC	Positive at 75 ng/mL	67%
11-Nor-Δ^9-Tetrahydrocannabinol	Positive at 50 ng/mL	100%
11-Hydroxy-Δ^9-Tetrahydrocannabinol	Positive at 5,000 ng/mL	1%
11-Nor-Δ^8-Tetrahydrocannabinol	Positive at 50 ng/mL	100%
Δ^8-THC-COOH	Positive at 50,000 ng/mL	0.1%

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

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, the urine samples, with 1.000～1.035 specific gravity or urine samples with pH 4~9 were spiked with target drugs at 25% below and 25% above Cut-Off level, respectively. These samples were tested using three batches of each device for all formats. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different formats.

2. Comparison Studies

The method comparison for the One Step Marijuana Test, and the One Step Methamphetamine Test was performed in-house with three laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the table below:

THC

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)

Viewer A	Positive	0	0	0	13	26
	Negative	10	16	16	1	0
Viewer B	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Viewer C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

Discordant Results of THC Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	223	52	Negative
Viewer B	207	53	Negative
Viewer B	223	52	Negative
Viewer C	207	53	Negative
Viewer C	223	52	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Viewer B	Positive	0	0	0	11	26
	Negative	10	16	16	3	0
Viewer C	Positive	0	0	0	11	26
	Negative	10	16	16	3	0

Discordant Results of THC Casette

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	223	52	Negative
Viewer A	247	53	Negative
Viewer B	207	53	Negative
Viewer B	247	53	Negative
Viewer B	223	52	Negative
Viewer C	207	53	Negative
Viewer C	247	53	Negative
Viewer C	223	52	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and	Near Cutoff Positive by GC/MS (Between the cutoff	High Positive by GC/MS (greater than +50%)

				cutoff)	and +50%)	
Viewer A	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Viewer B	Positive	0	0	0	11	26
	Negative	10	16	16	3	0
Viewer C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

Discordant Results of THC Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	223	52	Negative
Viewer A	247	53	Negative
Viewer B	207	53	Negative
Viewer B	247	53	Negative
Viewer B	223	52	Negative
Viewer C	207	53	Negative
Viewer C	247	53	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	26
	Negative	10	16	16	1	0
Viewer B	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Viewer C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

Discordant Results of THC Dip Card

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	223	52	Negative
Viewer B	207	53	Negative
Viewer B	223	52	Negative
Viewer C	207	53	Negative
Viewer C	247	53	Negative

MET

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Viewer B	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Viewer C	Positive	0	0	0	12	27
	Negative	10	19	15	1	0

Discordant Results of MET Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	133	1008	Negative
Viewer B	123	1003	Negative
Viewer B	133	1008	Negative
Viewer C	133	1008	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Viewer B	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Viewer C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

Discordant Results of MET Cassette

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	123	1003	Negative
Viewer A	133	1008	Negative
Viewer B	123	1003	Negative
Viewer C	123	1003	Negative
Viewer C	133	1008	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Viewer B	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Viewer C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

Discordant Results of MET Dip Card

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	123	1003	Negative
Viewer A	133	1008	Negative
Viewer B	123	1003	Negative
Viewer B	133	1008	Negative
Viewer C	123	1003	Negative
Viewer C	133	1008	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Viewer B	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Viewer C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

Discordant Results of MET Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	123	1003	Negative
Viewer B	123	1003	Negative
Viewer C	123	1003	Negative
Viewer C	133	1008	Negative

Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons. For a typical Strip device study, participants were 54 females and 86 males tested the Marijuana samples, and

54 females and 86 males tested the Methamphetamine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled samples and a device. The typical results are summarized below. There are no statistic differences of layperson results between different formats of the devices.

Typical Comparison between GC/MS and Lay Person Results (THC)

% of Cutoff	Number of samples	THC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	12.5	0	20	100%
-50% Cutoff	20	25	0	20	100%
-25% Cutoff	20	37.5	1	19	95%
+25% Cutoff	20	62.5	19	1	95%
+50% Cutoff	20	75	20	0	100%
+75% Cutoff	20	87.5	20	0	100%

Typical Comparison between GC/MS and Lay Person Results (MET)

% of Cutoff	Number of samples	MET Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	2	18	90%
+25% Cutoff	20	1250	19	1	95%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

3. Clinical Studies

   Not applicable

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that the Healgen THC One Step Marijuana Test, and Healgen mAMP One Step Methamphetamine Test are substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

HEALGEN SCIENTIFIC, LLC
C/O JOE SHIA
504 EAST DIAMOND AVE.
SUITE F
GAITHERSBURG MD 20877

Re: K140546
Trade/Device Name: Healgen THC One Step Marijuana Test
Healgen mAMP One Step Methamphetamine Test
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: II
Product Code: LDJ, LAF
Dated: April 17, 2014
Received: April 18, 2014

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140546

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

Indications for Use *(Describe)*
Healgen THC One Step Marijuana Test is an immunochromatographic assay for the qualitative determination of 11-nor-Δ9-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 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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