510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number
K253705

B Applicant
Healgen Scientific, LLC

C Proprietary and Established Names
Healgen® Accurate Oral Fluid Drug Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DKZ	Class II	21CFR 862.3100, Amphetamine Test System	Toxicology (91)
DIO	Class II	21 CFR 862.3250, Cocaine and metabolites TEST System	Toxicology (91)
LDJ	Class II	21 CFR 862.3870, Cannabinoids Test System	Toxicology (91)
DJC	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
LCM	Class II	Unclassified, Enzyme immunoassay Phencyclidine	Toxicology (91)
DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)
DJR	Class II	21 CFR, 862.3610 Methadone Test System	Toxicology (91)

II Submission/Device Overview:

A Purpose for Submission:
New device.

B Measurands:
Amphetamine, Cocaine, Marijuana, Methadone, Methamphetamine, Opiates, Oxycodone and Phencyclidine

C Type of Test:
Qualitative, lateral flow immunochromatographic

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Healgen® Accurate Oral Fluid Drug Test is a competitive binding lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Methadone, Methamphetamine, Opiates, Oxycodone , and Phencyclidine in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoylecgonine	20
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	d-Methamphetamine	50
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20

Phencyclidine (PCP)	Phencyclidine	10

This test provides only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/ Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. It is not intended to distinguish between prescription use or abuse of the drug. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Special Conditions for Use Statement(s):

For prescription point-of-care use only

C Special Instrument Requirements:

Not appliable; the device is a visually read single use device.

IV Device/System Characteristics:

A Device Description:

The Healgen Accurate Oral Fluid Drug Test is a rapid immunoassay based on the principle of competitive inhibition binding. Therefore, drugs that may be present in the oral fluid specimen compete for antibody binding sites with drugs or metabolites which may be present in the oral fluid specimen.

The test strip consists of a membrane strip with an immobilized drug conjugate. A colloidal gold labeled antibody complex is dried to one end of the membrane. A control line comprised of a different antibody/antigen reaction is present on the membrane strip. The control line is not influenced by the presence or absence of a drug analyte in the oral fluid and therefore it should be present in all reactions.

B Principle of Operation:

The Healgen® oral fluid drug test device is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody. During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region. A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line

region because of the absence of drug competition. 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Premier Biotech OralTox® Oral Fluid Drug Test,

B Predicate 510(k) Number(s):
k181305

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253705	K181305
Device Trade Name	Healgen® Accurate Oral Fluid Drug Test	Premier Biotech OralTox® Oral Fluid Drug Test
General Device Characteristic Similarities	K253705	K181305
Intended Use/Indications For Use	For the qualitative determination of drug analytes in human oral fluid.	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays	Same
Type of Test	Qualitative	Same
Specimen Type	Human Oral fluid	Same
Cut-Off Values	AMP 50 ng/mL COC 20 ng/mL THC 40 ng/mL MET 50 ng/mL OPI 40 ng/mL PCP 10 ng/mL OXY 20 ng/mL MTD 30 ng/mL	Same
Intended Use	For prescription use	Same
General Device Characteristic Differences		
Device Format	Rectangular prism shaped	Half cylinder-shaped

	cup	cup

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:

Precision-Reproducibility-Cut-Off studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. Testing was performed across three sites by 3 healthcare professionals at each site.

The samples were prepared by spiking target drug in negative oral fluid samples. Each drug concentration was confirmed by LC/MS/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device lot in a randomized order.

The following are summaries:

AMP

Results Device Lot	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LC-MS	*0*	*12.2*	*26.0*	*37.1*	*51.0*	*64.6*	*77.1*	*87.8*	*101.2*
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-

COC

Results Device Lot	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LC-MS (ng/mL)	*0*	*5.3*	*10.2*	*16.2*	*21.3*	*26.8*	*31.9*	*35.2*	*40.7*
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-

MET

Results Device Lot	-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
LC-MS (ng/mL)	*0*	*12.2*	*25.3*	*36.7*	*50.2*	*62.3*	*78.0*	*87.0*	*99.1*
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	28-/22+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

MTD

Results Device Lot	-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
LC-MS (ng/mL)	*0*	*7.8*	*15.8*	*23.4*	*31.6*	*38.2*	*44.5*	*52.9*	*59.7*
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-

OPI

Results Device Lot	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LC-MS (ng/mL)	*0*	*10.4*	*20.7*	*30.4*	*40.1*	*51.4*	*61.2*	*70.8*	*81.7*
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-

OXY

Results Device Lot	-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
LC-MS (ng/mL)	*0*	*5.4*	*10.6*	*15.7*	*20.4*	*25.2*	*32.8*	*37.8*	*43.6*
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

PCP

Results Device Lot	-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
LC-MS (ng/mL)	*0*	*2.7*	*5.3*	*8.0*	*10.7*	*13.2*	*16.0*	*18.8*	*21.5*
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	49+/1-	50+/0-	50+/0-	50+/0-

THC

Result Device Lot	-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
LC-MS (ng/mL)	*0*	*10.3*	*20.7*	*30.8*	*41.3*	*51.1*	*60.7*	*72.8*	*80.2*
Lot 1:	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2:	50-/0+	50-/0+	50-/0+	48-/2+	28-/22+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3:	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-

2. Linearity:

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

3. a. Interference:

Potential interfering substances were added to drug-free oral fluid and target drugs oral fluid with concentrations at 50% below and 50% above Cut-Off levels. These oral fluid

samples were tested using three batches of the Healgen device. Compounds that showed no interference for drugs at a concentration of 100 µg/mL are summarized in the following tables.

Acetaminophen	Deoxycorticosterone	Naproxen
Acetylcodeine	Dextromethorphan	Nicotinamide
Allobarbital	Digoxin	Nicotine
Alprazolam	Diltiazem HCl	Noscapine
Amobarbital	Diphenhydramine HCl	Omeprazole
Apomorphine	DL-Propranolol	Papaverine
Atenolol	Estradiol	Pentazocine
Atropine	Estrone	Phenytoin
Baclofen	Fluconazole	Pioglitazone HCl
Benzocaine	Furosemide	Prednisolone
Butabarbital	Hexobarbital	Prednisone
Caffeine	Hydrochlorothiazide	Procainamide HCl
Carbamazepine	Ibuprofen	Promethazine
Chlordiazepoxide	Imipramine	Quinine HCl
Chlorpromazine	Lamotrigine	R,R(-)-Pseudoephedrine
Cimetidine	Levetiracetam	Salicylic Acid
Citalopram HBr	Lidocaine	Sertraline HCL
Clobazam	Lormetazepam	Simvastin
Clomipramine	L-Thyroxine	Theophylline
Clonazepam	Metformin HCl	Thiamine
Clonidine	Methylphenidate HCl	Topiramate
Clopidogrel bisulfate	Metoprolol	Valproic Acid
Cortisol	Metronidazole	Verapamil
Cotinine	Montelukast sodium salt	Zonisamide
d,l-Salbutamol	Naltrexone HCl (except for OXY)	Dihydrocodeine (except for OPI & OXY)

Doxylamine	Ecgonine methylester (except for COC)	Phentermine (except for AMP)
Naloxone HCl (except for OXY		

Food items such as methanol cough drops, cough syrup, cola, mouthwash, coffee, tea, milk, sugar, chewing gum, alcohol, baking soda, salt, cranberry juice, orange juice, food coloring (red, blue, green), toothpaste, tomatoes and MSG were added in either drug-free oral fluid or oral fluid containing the target drugs with concentrations of 50% below and 50% above cutoff levels to a concentration of 5%. No discrepant results were observed.

Hemoglobin was added to drug-free oral fluid and oral fluid containing the target drugs AMP, COC, THC, MTD, MET, OPI, OXY and PCP with concentration of 50% below and 50% above cutoff levels to a concentration of 10mg/dL. Hemoglobin showed no interference at 10mg/dL.

Potential interference from cigarette smoking was evaluated by asking a participant to smoke a cigarette and after 15 minutes an oral fluid sample was collected and spiked with drugs at concentrations +/-50 % of cutoff. No interference was observed.

b. Analytic specificity

To test specificity, drug metabolites and other components that are likely to interfere in oral fluid samples were tested using three batches of the Healgen device. The following are summaries:

Drug	Concentration (ng/mL)	% Cross-Reactivity
AMPHETAMINE (AMP)		
D-Amphetamine	50	100%
l-Amphetamine	2,500	2%
d/l-Amphetamine	100	50%
Methylenedioxyamphetamine (MDA)	62.5	80%
3-Hydroxy Tyramine	2,500	2%
d,l-Phenylpropanolamine	10,000	0.5%
Phenethylamine	1,000	5%
Phentermine	12,500	0.4%
d-Methamphetamine	50,000	0.1%
l-Methamphetamine	50,000	0.1%
Hydroxyamphetamine	12,500	0.4%
Dimethylamylamine (DMAA)	50,000	0.1%
Methoxyamphetamine	200	25%
Benzodioxolylbutanamine(BDB)	10,000	0.5%
d,l-p-Chloramphetamine	300	16.7%
Methylenedioxyethylamphetamine	>100,000	<0.05%
Methylenedioxymethamphetamine	>100,000	<0.05%
Methylbenzodioxolylbutanamine	>100,000	<0.05%
para-Methoxymethamphetamine	>100,000	<0.05%
Phendimetrazine	>100,000	<0.05%
Phenmetrazine	>100,000	<0.05%
Ephedrine (d-,or l-,or d-l form)	>100,000	<0.05%
d-Pseudoephedrine	>100,000	<0.05%
Isoxsuprine	>100,000	<0.05%
l-Pseudoephedrine	>100,000	<0.05%
Fenfluramine	>100,000	<0.05%
Mephentermine	>100,000	<0.05%
COCAINE (COC)		
Benzoylecgonine	20	100%
Cocaine	20	100%

Cocaethylene	25	80%
Ecgonine methylester	12,500	0.16%
Norcocaine	500	4%
Procaine	>100,000	<0.02%
MARIJUANA (THC)		
Δ^9-Tetrahydrocannabinol	40	100%
11-nor-Δ^9-THC-9 COOH	4	1000%
Δ^8-Tetrahydrocannabinol	80	50%
11-hydroxy-Δ^9-THC	45	89%
Cannabinol	200	20%
Cannabidiol (CBD)	2,200	1.8%
11-Nor-Δ^9-THC-carboxy-glucuronide	60	66.7%
(+)-11-nor-9-carboxy-Δ^9-THC	50	80%
11-nor-Δ^8-THC-9-COOH	20	200%
8-beta-11-dihydroxy-Δ^9-THC	200	20%
8-beta-hydroxy-Δ^9-THC	200	20%
Exo-THC	75	53.3%
l-11-Nor-Δ^9-THC-9-Carboxylic Acyl-Glucuronide	15	266.7%
Δ^8-THC Carboxylic Acid	20	200%
Δ^9-THC Carboxylic Acid	4	1000%
(-)-Δ^9-THC-D3	3,000	1.3%
11-Nor-9beta-hydroxyhexahydrocannabinol (11-Nor-9beta-HHC) solution	125	32%
METHADONE (MTD)		
Methadone	30	100%
Phencyclidine	5,000	0.6%
LAAM	10,000	0.3%
Alpha-Methadol	150	20%
Doxylamine	>100,000	<0.03%
2-Ethylidene-1,5-dimethyl-3,3-diphenyl(EDDP) pyrrolidine(EDDP)	>100,000	<0.03%

2-Ethyl-5-methyl-3,3-diphenyl pyrrolidine(EMDP)	>100,000	<0.03%
METHAMPHETAMINE (MET)		
d-Methamphetamine	50	100%
l-Methamphetamine	1,250	4%
Methoxymethamphetamine	25	200%
Ephedrine	800	6.25%
Phenylephrine	4,000	1.25%
Procaine	2,000	2.5%
Methylephedrine	5,000	1%
Methylenedioxyethylamphetamine	250	20%
3,4-methylenedioxy-methamphetamine(MDMA)	50	100%
d-Amphetamine	25,000	0.2%
3,4-methylenedioxyamphetamine	25,000	0.2%
(±)-Amphetamine	10,000	0.5%
l-Amphetamine	>100,000	<0.05%
OPIATES (OPI)		
Morphine	40	100%
Acetylmorphine	50	80%
Codeine	10	400%
Ethylmorphine	24	166.7%
Heroin(diacetylmorphine)	50	80%
Hydromorphone	100	40%
Thebaine	1,500	2.67%
Norcodeine	1,500	2.67%
Oxycodone	25,000	0.16%
Oxymorphone	25,000	0.16%
Nalorphine	10,000	0.4%
Hydrocodone	100	40%

6-monoacetylmorphine(6-AM)	25	160%
Morphine 3- β-d-glucuronide	50	80%
Bilirubin	3,500	1.14%
Dihydrocodeine	50	80%
Normorphine	12,500	0.32%
Morphine-6-β-d-glucuronide	100	40%
OXYCODONE (OXY)		
Oxycodone	20	100%
Hydrocodone	1,562.5	1.28%
Hydromorphone	750	2.67%
Naloxone HCl	5,000	0.4%
Oxymorphone	48.8	40.98%
Dihydrocodeine	3,125	0.64%
Naltrexone HCl	2,000	1%
Heroin(diacetymorphine)	12,500	0.16%
Buprenorphine	>100,000	<0.02%
Codeine	>100,000	<0.02%
Morphine	>100,000	<0.02%
Morphine 3- β-d-glucuronide	>100,000	<0.02%
Ethylmorphine	>100,000	<0.02%
6-monoacetylmorphine(6-AM)	>100,000	<0.02%
PHENCYCLIDINE (PCP)		
Phencyclidine	10	100%
Cyclizine	5,000	0.2%
Venlafaxine	50,000	0.02%
Tenocyclidine (TCP)	2,000	0.5%
l-(l-phenylcyclohexyl) morpholine	15	66.7%
4-hydroxyphencylidine	10	100%
Hydrocodone	>100,000	<0.01%
Hydromorphone	>100,000	<0.01%
Nalorphine	>100,000	<0.01%
EDDP	>100,000	<0.01%
Ketamine	>100,000	<0.01%

Prazepam	>100,000	<0.01%
Amitriptyline	>100,000	<0.01%
(+) Brompheniramine	>100,000	<0.01%
(+) Chlorphenamine	>100,000	<0.01%
Desmethylvenlafaxine	>100,000	<0.01%
Chlorpromazine	>100,000	<0.01%
Clomipramine	>100,000	<0.01%
Cyclobenzaprine	>100,000	<0.01%
Dextromethorphan	>100,000	<0.01%
Doxepin	>100,000	<0.01%
Doxylamine	>100,000	<0.01%
Imipramine	>100,000	<0.01%
Thioridazine	>100,000	<0.01%
Dexbrompheniramine	>100,000	<0.01%

c. Effect of Oral fluid pH

To investigate the effect of oral fluid pH, oral fluid samples with pH 4 to 9 were spiked with target drugs at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of the device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off.

d. Drug Recovery Study

Volume Recovery

A sample volume recovery study was conducted to confirm that adequate sample volume could be extracted from the device for confirmatory testing after collection and shipping. Operators collected samples from volunteers at the study site. Three lots of the Healgen® test device was used on a total of 150 subjects (53 normal volunteers and 67 drug users) following the device's instructions for use. The results showed that the saturation indicator appeared within 7 minutes and that the average sample volume was 2.2±0.2mL.

Analyte Recovery

To confirm that preliminary positive results can be adequately measured via confirmation testing after being subject to the temperature conditions required for shipping and storage, negative oral fluid samples in glass bottles were spiked with target drugs, Amphetamine, Cocaine, Marijuana (THC), Methamphetamine, Opiates, Phencyclidine, Oxycodone and Methadone to concentrations approximately -50% and +50% of the cutoff. Samples were spiked using known standards. Each drug concentration was confirmed by LC-MS/MS. The samples were transferred to Healgen devices using the collection sponges soaked into the spiked sample for up to 7 minutes. The 7 minutes was choosing because the saturation indicator appeared within 7 minutes during sample volume study.

For each of 3 storage conditions (2-8°C, at -20°C and at 40°C) 12 devices were used (4 devices from each of 3 lots). For each device, drug was measured by LC-MS/MS at time zero and the devices containing the specimens were stored under the specified condition. Drug in the devices stored at 2- 8°C was measured by LC-MS/MS at 0, 3, 7, and 10 days, drug in the devices stored at -20°C was measured by LC-MS/MS at 0 and 100 days, and drug in the devices stored at 40°C, measured at 0 and 1 day.

Over 90% recoveries were observed for the drugs in the Healgen devices. Oral fluid samples can be stored in the device at -20ºC for at least 100 days. Oral fluid samples can be shipped overnight in the device for LC-MS confirmation

The minimum and maximum recovery from the 12 devices per lot per storage condition is shown below:

Room Temperature (20 to 25°C) (3-day storage)

-50% cutoff	**AMP 25**	**COC 10**	**MET 25**	**MTD 15**	**OPI 20**	**OXY 10**	**PCP 5**	**THC 20**
MAX	107.05%	98.13%	109.77%	102.80%	105.55%	109.55%	97.51%	106.12%
MIN	93.32%	91.16%	93.58%	98.67%	91.19%	97.06%	91.54%	93.81%
+50% cutoff	**AMP 75**	**COC 30**	**MET 75**	**MTD 45**	**OPI 60**	**OXY 30**	**PCP 15**	**THC 60**
MAX	109.38%	109.47%	109.66%	107.71%	105.76%	108.91%	98.00%	108.44%
MIN	102.87%	95.44%	104.06%	100.46%	92.56%	101.85%	92.67%	94.44%

-20°C (100-day storage)

-50% cutoff	**AMP 25**	**COC 10**	**MET 25**	**MTD 15**	**OPI 20**	**OXY 10**	**PCP 5**	**THC 20**
MAX	109.27%	98.81%	108.91%	100.00%	108.28%	98.04%	105.58 %	106.12%
MIN	98.31%	90.26%	91.13%	92.72%	96.18%	91.18%	91.54%	100.00%
+50% cutoff	**AMP 75**	**COC 30**	**MET 75**	**MTD 45**	**OPI 60**	**OXY 30**	**PCP 15**	**THC 60**
MAX	95.63%	103.07%	108.95%	101.96%	103.82%	100.68%	103.65%	108.90%
MIN	92.62%	95.00%	97.92%	96.30%	91.74%	93.19%	92.67%	92.57%

40°C (1-day storage)

-50% cutoff	**AMP 25**	**COC 10**	**MET 25**	**MTD 15**	**OPI 20**	**OXY 10**	**PCP 5**	**THC 20**
MAX	108.30%	105.83%	109.58%	105.12%	105.01%	104.90%	106.67%	109.37%
MIN	95.44%	94.29%	92.83%	98.05%	93.61%	96.45%	98.46%	96.29%
+50% cutoff	**AMP 75**	**COC 30**	**MET 75**	**MTD 45**	**OPI 60**	**OXY 30**	**PCP 15**	**THC 60**
MAX	103.68%	107.00%	109.76%	104.55%	102.43%	102.42%	109.03%	107.12%
MIN	99.12%	99.75%	106.56%	99.67%	95.84%	93.73%	103.60%	92.0 %

4. Detection Limit and Assay Reportable Range:

Refer to Precision/Reproducibility section under VII A.1 above

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
The device is traceable to commercial standards. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims that the devices are stable at 2-30 °C for 24 months based on the real time stability study at 2°C and 30°C.

6. Assay Cut-Off:
Characterization of how the device performs analytically around the claimed cut-off concentration appears in the precision section VII. A.1 above.

B Comparison Studies:

1. Method Comparison with Predicate Device:
Method comparison studies for the Healgen® Accurate Oral Fluid Drug Test were performed, testing a total of 1430 samples at six testing sites from nine lots. The number of operators at each site varied between one and thirteen health care professionals. Four sites were within the US, while 2 sites were OUS.
Device results were compared to LC/MS/MS results. Samples were collected and stored with the candidate device for the confirmatory LC-MS/MS testing.
The results are presented in the tables below:

AMP

Concentration range by LC/MS	Number of samples	Number of Negative	Number of Positive	The percentage of correct result
Drug free (0 %)	833	833	0	100%
< -50% Cut off	261	261	0	100%
-50% Cut off ~ Cut off	31	30	1	97%
Cut off ~ +50% Cut off	14	2	12	86%
> -50% Cut off	95	0	95	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA02-043	41.377	Pos
HA03-096	52.62	Neg
HA01-188	56.82	Neg

COC

Concentration range by LC/MS	Number of samples	Number of Negative	Number of Positive	The percentage

				of correct result
Drug free	833	833	0	100%
< -50% Cut off	176	176	0	100%
-50% Cut off ~ Cut off	21	17	4	81%
Cut off ~ +50% Cut off	23	2	21	91%
> -50% Cut off	181	0	181	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA02B-020	16.55	Pos
HA02-075	16.788	Pos
HA03-026	17.037	Pos
HA02-038	19.574	Pos
HA01-121	22.596	Neg
HA02B-104	22.60	Neg

MTD

Concentration range by LC/MS	**Number of samples**	**Number of Negative**	**Number of Positive**	**The percentage of correct result**
Drug free	1040	1040	0	100%
< -50% Cut off	223	223	0	100%
-50% Cut off ~ Cut off	19	18	1	95%
Cut off ~ +50% Cut off	11	1	10	91%
> -50% Cut off	32	0	32	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
WA011	28.8	Pos
HA01-297	33.04	Neg

MET

Concentration range by LC/MS	**Number of samples**	**Number of Negative**	**Number of Positive**	**The percentage of correct result**
Drug free	838	838	0	100%
< -50% Cut off	296	296	0	100%

-50% Cut off ~ Cut off	30	29	1	97%
Cut off ~ +50% Cut off	17	0	17	100%
> -50% Cut off	55	0	55	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA01-149	41.36	Pos

OPI

Concentration range by LC/MS	**Number of samples**	**Number of Negative**	**Number of Positive**	**The percentage of correct result**
Drug free	799	799	0	100%
< -50% Cut off	233	233	0	100%
-50% Cut off ~ Cut off	28	27	1	96%
Cut off ~ +50% Cut off	12	1	11	92%
> -50% Cut off	162	0	162	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA02-119	33.62	Pos
HA01-201	42.81	Neg

OXY

Concentration range by LC/MS	**Number of samples Total**	**Number of Negative**	**Number of Positive**	**The percentage of correct result**
Drug free	854	854	0	100%
< -50% Cut off	269	269	0	100%
-50% Cut off ~ Cut off	16	16	0	100%
Cut off ~ +50% Cut off	39	1	38	97%
> -50% Cut off	56	0	56	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA03-344	22.53	Neg

PCP

Concentration range by LC/MS	Number of samples Total	Number of Negative	Number of Positive	The percentage of correct result
Drug free	1023	1023	0	100%
< -50% Cut off	233	233	0	100%
-50% Cut off ~ Cut off	23	23	0	100%
Cut off ~ +50% Cut off	15	0	15	100%
> -50% Cut off	47	0	47	100%

THC

Concentration range by LC/MS	Number of samples Total	Number of Negative	Number of Positive	The percentage of correct result
Drug free	725	725	0	100%
< -50% Cut off	252	252	0	100%
-50% Cut off ~ Cut off	91	87	4	96%
Cut off ~ +50% Cut off	25	11	14	56%
> -50% Cut off	141	0	141	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA01-288	35.42	Pos
HA03-097	37.094	Pos
HA03-103	38.145	Pos
HA02-071	38.982	Pos
HA01-141	40.67	Neg
HA03-030	40.680	Neg
HA02-100	40.95	Neg
HA03-145	43.409	Neg
HA02-166	43.91	Neg
HA01-081	44.868	Neg
HA01-035	45.231	Neg
HA02B-244	45.27	Neg
HA03-163	47.22	Neg
HA01-221	49.26	Neg
HA01-144	49.75	Neg

2. Matrix comparison:

Not applicable. These devices are of use with oral fluid samples only.

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable.

2. Clinical Specificity:
   Not applicable.

3. Clinical Cut-Off:

   Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Expected Values/Reference Range:
Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.