510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K252523

B Applicant

Healgen Scientific LLC

C Proprietary and Established Names

Healgen® Accurate Oral Fluid Drug Test COT/THC; Healgen® Accurate Oral Fluid Drug Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NFW, MKU	Class II	21 CFR 862.3870 - Cannabinoid Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:
Over-the-counter claim for predicate device k223162

B Measurand:
Cotinine and marijuana

C Type of Test:
Lateral flow chromatographic immunoassay

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 COT/THC is a lateral flow chromatographic immunoassay for the qualitative detection of cotinine (COT) and/or marijuana (THC) in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Cotinine (COT)	(-) Cotinine	30
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40

This test provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Liquid chromatography mass spectrometry (LC/MS) is the preferred method for the confirmation test.

The Healgen® Accurate Oral Fluid Drug Test is a competitive binding lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Marijuana (THC) and Cotinine in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cut-off (ng/mL)
Cotinine (COT)	(-) Cotinine	30
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC/MS) and liquid chromatography mass spectrometry (LC/MS) are the preferred confirmatory methods.

C Special Conditions for Use Statement(s):

OTC – Over-the-Counter

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The Healgen® Accurate Oral Fluid Drug Test COT/THC and Healgen® Accurate Oral Fluid Drug Test are immunochromatographic assays that uses a lateral flow system for the qualitative detection of cotinine and marijuana in human oral fluid. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

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.

Kit Contents for the Device:

- Test device- Holder cartridge with cup insert, test strips and reagent pads
- Oral fluid (saliva) collection swab
- Identification Label
- Package Insert

B Principle of Operation:

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.

In the absence of THC and/or COT in the oral fluid specimen the colloidal gold-labeled antibody complex moves with the oral fluid by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the test area, The formation of two (2) visible lines (control and test lines) occurs when the test is negative or below the cut-off for the drug.

When THC and/or COT is present in the oral fluid specimen, the drug or metabolites will compete with the immobilized drug conjugate in the test area for the antibody binding sites on the colloidal gold-labeled antibody complex. If a sufficient drug analyte amount is present it will fill the available binding sites, thus preventing attachment of the drug labeled antibody to the drug conjugate.

The formation of one (1) visible line (control line, no test line) is indicative of a preliminary positive result for the drug. For a procedural control, a pink colored line will appear at the control line region, indicating that the proper volume of specimen was added and that membrane wicking occurred.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Healgen® Accurate Oral Fluid Drug Test, Healgen® Accurate Oral Fluid Drug Test COT

B Predicate 510(k) Number(s):
K223162

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252523	K223162
Device Trade Name	Healgen® Accurate Oral Fluid Drug Test COT/THC; Healgen® Accurate Oral Fluid Drug Test	Healgen® Accurate Oral Fluid Drug Test, Healgen® Accurate Oral Fluid Drug Test COT
General Device Characteristic Similarities		
Indications For Use	For the qualitative determination of cotinine and marijuana in human oral fluid	Same
Calibrators	Cotinine and Delta-9-Tetrahydrocannabinol	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays	Same
Type of test	Qualitative	Same
Specimen type	Human oral	Same
Cut-off Values	COT 30 ng/mL THC 40 ng/mL	Same
General Device Characteristic Differences		
Intended Use	For Over-the-Counter use	For prescription use

VI Standards/Guidance Documents Referenced:

ISO 10993-5:2009: Biological evaluation of medical devices - Part *5:* Tests for in vitro cytotoxicity.
ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

ISO 10993-12:2012: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   The precision/reproducibility was established in K223162.

2. Linearity:

   Nonapplicable.

3. Analytical Specificity/Interference:

   Specificity was established in K223162.

   Cross reactivity was established in K223162.

   Drug Recovery was established in K223162.

   Sample volume reproducibility was established in K223162.

   Read time was established in K223162.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The device is traceable to commercial standards.

6. Detection Limit:

See precision section for predicate k223162 section VII.A.1.

7. Assay Cut-Off:

Refer to precision section for predicate k223162 section VII.A.1.

B Comparison Studies:

1. Method Comparison with Predicate Device:
Method Comparison studies provided in k223162 support this device.

2. Lay User Studies:

Lay User studies for the Healgen® Accurate Oral Fluid Drug Test COT/THC; Healgen® Accurate Oral Fluid Drug Test were performed at three testing sites representative of intended use sites. A total of 160 lay users each received a spiked oral fluid sample to test with the Healgen Accurate Oral Fluid Drug Test device. Then, the same 160 lay users were paired and tested each other, for a total of 80 pairs of lay users and 160 tests. The spiked samples and 160 real samples were tested by LC/MS and results were compared with the lay user results.

An additional lay user study was performed for THC at another testing site representative of intended use sites. 98 lay users with diverse educational and professional backgrounds performed tests. The lay users were paired up to test each other. All lay users perform tests following instruction of the product insert. No one self-tested and each lay user had only one partner.

The results are presented in the tables below:

Spiked sample data results:

Data Summary According to THC Concentrations

Result / Device Lot	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cut
LC-MS (ng/mL)	0.00	9.5	20.7	30.2	51.4	59.2	68.3	81.5
Lot 1:	10-/0+	12-/0+	10-/0+	9-/1+	7+/0-	9+/0-	6+/0-	6+/0-
Lot 2:	3-/0+	3-/0+	3-/0+	1-/0+	1+/0-	3+/0-	3+/0-	3+/0-

Lot 3:	7-/0+	5-/0+	7-/0+	9-/0+	12+/0-	8+/0-	11+/0-	11+/0-
Negative	20	20	20	19	0	0	0	0
Positive	0	0	0	1	20	20	20	20
Total	20	20	20	20	20	20	20	20
Agreement (%)	100%	100%	100%	95%	100%	100%	100%	100%

Data Summary According to COT Concentrations

Result / Device Lot	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
LC-MS (ng/mL)	0.0	7.5	15.4	22.3	38.1	45.4	53.4	60.9
Lot 1:	6-/0+	10-/0+	12-/0+	10-/0+	10+/0-	7+/0-	9+/0-	6+/0-
Lot 2:	3-/0+	3-/0+	3-/0+	3-/0+	1+/0-	1+/0-	3+/0-	3+/0-
Lot 3:	11-/0+	7-/0+	5-/0+	7-/0+	9+/0-	12+/0-	8+/0-	11+/0-
Negative	20	20	20	20	0	0	0	0
Positive	0	0	0	0	20	20	20	20
Total	20	20	20	20	20	20	20	20
Agreement (%)	100%	100%	100%	100%	100%	100%	100%	100%

Native sample data results

Data Summary According to THC Concentrations

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct results
Drug free	155	0	155	100%
< -50% Cut off	8	0	8	100%
-50% Cut off ~ Cut off	17	1	18	94.4%
Cut off ~ +50% Cut off	5	33	38	86.8%
> +50% Cut off	0	39	39	100%

Data Summary According to COT Concentrations

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct results
Drug free	45	0	45	100%
<-50% Cut off	13	0	13	100%
-50% Cut off ~ Cut off	17	2	19	89.5%
Cut off ~ +50% Cut off	1	12	13	92.3%
> +50% Cut off	0	70	70	100%

3. Matrix Comparison:

Not Applicable

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

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

Not applicable.

D Clinical Cut-Off:

Not applicable.

E 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 is adequate to support an SE decision.