



Accurate™ Oral Fluid Drug Test

Instructions For Use

A rapid, screening test for the simultaneous, qualitative detection of Cotinine and Marijuana in human oral fluid.

For prescription use only.

For *in vitro* diagnostic use only.

INTENDED USE

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 test provides only a preliminary result. A more specific alternative chemical method should be used to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography / Mass Spectrometry (GC-MS), Liquid Chromatography / Mass Spectrometry (LC-MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drug screen test result, particularly when evaluating preliminary positive results.

SUMMARY

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 against their respective drug conjugate 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 the drug competition, while a drug negative oral fluid specimen will generate a line in the test line region due to the absence of drug competition.

For a procedural control, a pink colored line will always appear at the control line region, indicating proper specimen volume was added and membrane wicking occurred.

A presumptive positive test result does not always mean that a person took illegal drugs, and a negative test result does not always mean that a person did not take illegal drugs. There are several factors that influence the reliability of the test results. There is a possibility that other substances and/or factors may interfere with the test and cause incorrect test results.

REAGENTS

The Healgen® Accurate™ Oral Fluid Drug Test contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For prescription and professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The oral fluid test device should remain in the sealed pouch until use.

- The oral fluid specimen should be collected using the collector provided with the Healgen® Accurate™ Oral Fluid Drug Test. No other collection devices should be used with this test.
- The used collector and device should be discarded according to local regulations.
- Do not reuse tests.
- Professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

STORAGE AND STABILITY

- DO NOT FREEZE.
- Store as packaged in the sealed pouch either at room temperature or refrigerated [4-30°C (39-86°F)].
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch before use.
- Keep away from direct sunlight, moisture, and heat.
- Do not use beyond the expiration date.

MATERIALS

Materials Provided

- Test devices
- Oral fluid (saliva) collectors
- Security seal labels
- Instructions For Use

Materials Required but Not Provided

- Timer, clock, or watch
- Disposable gloves
- Quality Controls

SPECIMEN COLLECTION

- The oral fluid drug test is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions provided in Directions For Use section below.
- Perform testing immediately after specimen collection.

DIRECTIONS FOR USE

Allow the test device to come to room temperature [15-30°C (59-86°F)] prior to testing.

Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to specimen collection.

Do not bite, suck, or chew on the collection swab.

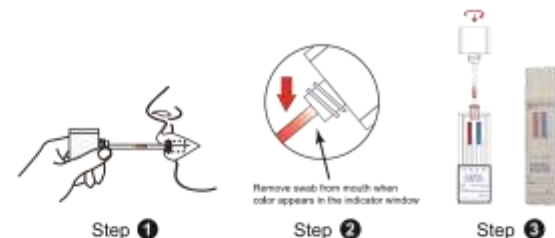
- Remove the collection swab from the packaging. Relax the mouth and insert the collection swab horizontally into the mouth. Sweep the inside of the mouth (cheek, gums, and tongue) using a circular motion. (Step 1).
- Hold the swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab (Step 2). Keep collection swab horizontal to ensure sufficient oral fluid is collected.

Important: After 7 minutes, if the saturation indicator does not turn color, discard the device and repeat the test.

- Remove the test device from the sealed pouch and place upright on a clean, flat surface. Remove the collection swab from mouth. Keeping the test device upright, gently and slowly insert the collection swab into the test device, swab end first, until the swab reaches the bottom of the test device. Screw downward until the locking flange locks in place. The cube must remain upright on a flat surface for test to run.

NOTE: Once the collection swab locks in place, the device is airtight, tamper evident, and ready for disposal or sent to a laboratory for confirmation testing (on presumptive positive result).

- Set a timer for 10 minutes. Wait for the colored bands to appear in the test results area (See "Interpretation of Results" section below). Results for any single analyte can be read as negative as soon as two lines appear on the analyte strip. Read presumptive positive results at 10 minutes.



NOTES AND TROUBLESHOOTING

- If invalid results occur or the strips do not wick, peel off the label (as marked at bottom of the device) to check if either there is enough specimen, or if the oral fluid is too thick to run.
 - If strips do not appear to flow when there is enough oral fluid, or the oral fluid is too thick to run, move the device back and forth several times across a flat, clean surface. Ensure the device remains upright. Do not tilt the device when the test is running before reading results.
 - Oral fluid tends to form air bubbles which sit at the bottom of the strip and prevent the strip from running. Gently tap the device on the table or counter surface popping the air bubble allowing capillary action to begin, thus initiating the test.
- If the indicator strip has not turned red after 7 minutes, discard and begin collection and testing with new product. Instruct the donor to rotate the swab in a circular motion while swabbing each area of the mouth until the saturation indicator activates.

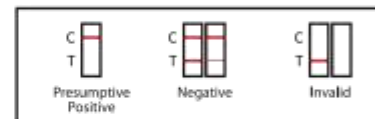
INTERPRETATION OF RESULTS

PRESUMPTIVE POSITIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T). A positive result indicates the drug concentration exceeds the detectable level.

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

Negative results can be read as soon as test and control line appear on any strip (often within 2 minutes). A negative result indicates the drug concentration is below the detectable level.

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the test immediately.



UNDERSTANDING THE TEST RESULTS

- A presumptive positive test result does not always mean a person took illegal drugs, and a negative test result does not always mean a person did not take illegal drugs. Several factors influence the reliability of drug tests.

IMPORTANT: The result you obtained is called presumptive for a reason. The sample must be tested by laboratory to determine if a drug of abuse is actually present in the sample.⁷

- What is a False Positive Test?

The definition of a false positive test would be an instance where the oral fluid test is positive even though target drugs are not in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

3. What Is a False Negative Test?

The definition of a false negative test is that the initial target drugs are present but are not detected by an oral fluid drug test.

LIMITATIONS

- The Healgen® Accurate™ Oral Fluid Drug Test provides only a qualitative preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography mass spectrometry (GC-MS) and liquid chromatography mass spectrometry/mass spectrometry (LC-MS/MS) are the preferred confirmatory methods.
- There is a possibility that other substances and/or factors not listed below may interfere with the test and cause incorrect results (e.g., technical or procedural errors). Insufficient specimen volume, incorrect operating procedure, or expired tests are the most likely reasons for control band failure.
- This test has been developed for testing human oral fluid only. Do NOT use this device to test any other fluids.
- A positive result does not indicate level of intoxication, administration route, or concentration in oral fluid. A positive result might be obtained from certain foods or food supplements.
- A negative result may not necessarily indicate drug-free oral fluid. Negative results can be obtained when drug is present but below the cutoff level of the test.
- The test does not distinguish between drugs of abuse and certain medications.

QUALITY CONTROL

- The Healgen® Accurate™ Oral Fluid Drug Test provides a built-in control band for each test strip to indicate that the test has performed correctly. The control band should always appear, regardless of the presence of drugs, to confirm sufficient sample volume, adequate membrane wicking, and correct procedural technique.
- Control materials are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be performed with each new lot, each new shipment, and every thirty days to check storage. Positive and Negative Salivabuse™ Oral Fluid Controls are available from Biochemical Diagnostics, Inc. (+1-800-223-4835) and are recommended to be used.
- Positive or Negative Salivabuse™ Oral Fluid Control (1.0 mL) may be directly pipetted into the cup for control testing. Only one sample, either a control or a patient sample, can be tested each time.

PERFORMANCE CHARACTERISTICS

Accuracy

Accuracy of the Healgen® Accurate™ Oral Fluid Drug Test was established by analyzing 539 clinical oral fluid specimens in parallel with LC-MS/MS. The sensitivity of the Healgen® Accurate Oral Fluid Drug Test was determined by tested LC-MS/MS confirmed drug concentration at negative, <-50% cutoff, -50% cutoff-cutoff, cutoff+50% cutoff, and >+50% cutoff. The results are summarized below:

COT

% of Cutoff	Number of Samples	Operator results		The percentage of correct results (%)
		# Positive	# Negative	
Drug-Free	112	0	112	100
Less than Half the Cutoff	93	0	93	100
Near Cutoff Negative	40	5	35	87.5
Near Cutoff Positive	32	25	4	87.5
High Positive	150	150	0	100

THC

% of Cutoff	Number of Samples	Operator results		The percentage of correct results (%)
		# Positive	# Negative	
Drug-Free	35	0	35	100
Less than Half the Cutoff	13	0	13	100
Near Cutoff Negative	7	2	5	71.4
Near Cutoff Positive	10	6	4	60
High Positive	61	61	0	100

Specificity and Cross-Reactivity

The following table lists compounds that are positively detected in the Healgen® Accurate™ Oral Fluid Drug Test

Drug	Concentration (ng/mL)	%Cross-Reactivity
COTININE (COT 30)		
(-) Cotinine	30	100%
S(-)-Nicotine	3,000	1%
Trans-3-hydroxycotinine	10	300%
(+)-anabasine	1,350,000	0.002%
(+/-)-nornicotine	150,000	0.02%
Niacinamide	>100,000	< 0.03%
MARIJUANA (THC 40)		
Δ ⁹ -Tetrahydrocannabinol	40	100%
Δ ⁸ -Tetrahydrocannabinol	80	50%
11-nor-Δ ⁹ -THC-9 COOH	4	1000%
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%

Precision-Reproducibility-Cutoff

This study is performed 2 runs/day for each of the three lots and lasts 25 days at three intended user sites. The results are given below:

COTININE Concentration(ng/ml)	n	Lot 1		Lot 2		Lot 3	
		-	+	-	+	-	+
0	50	50	0	50	0	50	0
7.5	50	50	0	50	0	50	0
15	50	50	0	50	0	50	0
22.5	50	50	0	48	2	49	1
30	50	24	26	23	27	24	26
37.5	50	2	48	0	50	1	49
45	50	0	50	0	50	0	50
52.5	50	0	50	0	50	0	50

MARIJUANA Concentration(ng/ml)	n	Lot 1		Lot 2		Lot 3	
		-	+	-	+	-	+
		0	50	50	0	50	0
10	50	50	0	50	0	50	0
20	50	50	0	50	0	50	0
30	50	47	3	48	2	49	1
40	50	24	26	28	22	24	26
50	50	1	49	2	48	3	47
60	50	0	50	0	50	0	50
70	50	0	50	0	50	0	50
80	50	0	50	0	50	0	50

Effect of Oral Fluid pH

The pH of an aliquot of negative oral fluid is adjusted in the range of 4.00 to 9.00 in 1pH unit increments and spiked with the target drug at 50% below and 50% above Cutoff levels. The spiked, pH-adjusted oral fluid was tested with the Healgen® Accurate Oral Fluid Drug Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free oral fluid or drug-positive oral fluids. The following compounds show no cross-reactivity when tested with the Healgen® Accurate™ Oral Fluid Drug Test at a concentration of 100 µg/mL.

Acetaminophen	Diacetylmorphine	Naltrexone
(1R,2S)-(-)Ephedrine Hydrochloride	Diazepam	Naproxen
Acetylcodeine	Digoxin	Niacinamide
Acetylsalicylic Acid	Dihydrocodeine	Nicotinamide
Allobarbitol	Diltiazem HCl	Niordiazepam
Alprazolam	Diphenhydramine HCl	Noscapine
Amobarbitol	DL-Methadone	Ormeprazole
Ampicillin	DL-Propranolol	Papaverine
Apomorphine	Doxylamine	Penicillin
ascorbic acid	Ecgonine Hydrochloride	Pentazocine
Atenolol	Ecgonine methylester	Pentobarbitol
Atropine	Estradiol	Phencyclidine (PCP)
Baclofen	Estrone	Phenobarbitol
Benzocaine	Fenoprofen	Phentermine
Benzoylcegonine	Fluconazole	Phenylephrine
beta-Phenethylamine	Furosemide	Phenylpropanolamine
bilirubin	Gemfibrozil	Phenytol
Butabarbitol	Gentisic Acid	Pioglitazone HCl
Butalbital	Heroin hydrochloride	Prednisolone
Caffeine	Hexobarbitol	Prednisone
Carbamazepine	Hydrochlorothiazide	Procainamide HCl
Chlordiazepoxide	Hydrocodone	Procaine HCL
Chlorpromazine	Hydromorphone	Promethazine

Cimetidine	Ibuprofen	Pseudoephedrine
Citalopram HBr	Imipramine	Quinidine
Clobazam	L-Ephedrine	Quinine HCl
Clomipramine	L-Methamphetamine	R,R(-)- Pseudoephedrine
Clonazepam	L-Thyroxine	Salicylic Acid
Clonidine	Lamotrigine	Sertraline HCL
Clopidogrel bisulfate	Levetiracetam	Simvastin
Clorazepate	Lidocaine	Temazepam
Cocaehtylene	Lormetazepam	Theophylline
Cocaine	Meperidine	Theophylline
Codeine	Metformin HCl	Thiamine
Cortisol	Methylphenidate HCl	Topiramate
D-Amphetamine	Metoprolol	Valproic Acid
D-Methamphetamine	Metronidazole	Verapamil
d,l-Salbutamol	Montelukast sodium salt	Zomepirac
Deoxycorticosterone	Morphine Sulfate	Zonisamide
Delta-9-THC (except for THC test)	Nalorphine	
Dextromethorphan	Naloxone	

LITERATURE REFERENCES

1. Cone, EJ, "Saliva Testing for Drugs of Abuse," Ann NY Acad Sci, 1993; 694: pp120
2. Schramm W., et al. Drugs of Abuse in Saliva: A Review. J Anal Tox, 16 (1): 1-9, 1992.
3. Kidw II, D.A., Holland, J.C., Athanasellis, S. Testing for Drugs of Abuse in Saliva and Sweat. J. Chrom. B. 713: 111-135 (1998)
4. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 10th edition. Biomedical Publications, 2014.
5. Hawks RL, Chiang CN, eds. Oral Fluid Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute of Drug Abuse; 1986.
6. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988
7. McBay AJ. Drug analysis technology- pitfalls and problems of drug testing. Clin Chem 1987 Oct; 33 (11 Suppl):33B-40B.

INDEX OF SYMBOLS

MORE INFORMATION AND RESOURCES

A health care provider, or any of the following organizations listed below can be contacted for additional information and/or counseling regarding substance abuse prevention and treatment:

- American Council for Drug Education (ACDE) 1-800-DRUGHELP / www.acde.org
- Center for Substance Abuse Treatment (CSAT)1-877-SAMHSA-7 / www.samhsa.gov
- The National Council on Alcoholism and Drug Dependence (NCADD) 1-800-NCA-CALL / www.ncadd.org

ASSISTANCE

If you have any questions regarding the use of this product, please call our Technical Support Number 1-866-982-3818 (9:00a.m. to 5p.m. CDT).



Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

	Do not reuse		See Instruction for Use		Expiration Date	
	Tests per Kit		Store Between 4-30°C (39-86°F)		Keep Dry	
LOT	Batch Number	REF	Catalog#			
UDI	Unique Device Identifier	IVD	For <i>in vitro</i> diagnostic use only		Keep Away from Sunlight	
						Manufacturer