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Drugs & Alcohol Test

Multi-drug rapid test • cup • oral fluid

ENGLISH

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites and alcohol in human oral fluid. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

[INTENDED USE]

The Drugs & Alcohol Test for AMP/ COC/ OPI/MOP/ THC/ BZO/ KET & ALC is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoylecgonine	20
Opiates (OPI/MOP)	Morphine	25
Marijuana (THC)	11-nor-Δ9 -THC-9 COOH	12
Benzodiazepines (BZO)	Oxazepam	10
Ketamine (KET)	Ketamine	50
Alcohol (ALC)	Alcohol	0.02%

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 gas chromatography/tandem mass spectrometry (GC/MS) are the preferred confirmatory methods. Professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

[SUMMARY]

The Drugs & Alcohol Test for AMP/ COC/ OPI/MOP/ THC/ BZO/ KET & ALC and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilises monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid

Amphetamine (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected in oral fluid as early as 5-10 minutes following use[1]. Amphetamine can be detected in oral fluid for up to 72 hours after use[1].

Cocaine (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anaesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use[1]. Cocaine and benzoylecgonine can be detected in oral fluid for up to 24 hours after use[1].

Opiates (OPI/MOP)

The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation. Using the OPI test, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose[1]. Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in excreted unmetabolized, and is also the major metabolic product of codeine and heroin[2].

Marijuana (THC)

11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH), the metabolite of THC (Δ^9-tetrahydrocannabinol), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity[3]. Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use[3].

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception[1].

Ketamine (KET)

Ketamine is a dissociative anaesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anaesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behaviour, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained[4]. The effects of Ketamine generally last 4-6 hours following use.

Alcohol

Two-thirds of all adults drink alcohol[5]. The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions[6].

The Drugs & Alcohol Test Cup yields a positive result when the concentration of alcohol in oral fluid exceeds 0.02%.

[ASSAY PRINCIPLE]

The Drugs & Alcohol Test for AMP/ COC/ OPI/MOP/ THC/ BZO/ KET & ALC 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 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 coloured 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 coloured line will not form in the test line region.
A drug-positive oral fluid specimen will not generate a coloured 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 coloured line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[ALCOHOL PRINCIPLE]

The oral fluid Alcohol Rapid Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colours depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

[REAGENTS]

The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Cocaine, Opiates, Morphine, Δ^9-THC-COOH, Phencyclidine, Methadone, Methylenedioxymethamphetamine ,Oxycodone, Cotinine, Benzodiazepines, Ketamine, Barbiturate, Buprenorphin,Fentanyl, Tramadol, 6-mono-aceto-morphine, Carfentanyl, 3,4-methylenedioxypyrovalerone,alpha-Pyrrolidinovalerophenone, Lysergic acid diethylamide and Synthetic Marijuana.

[ALCOHOL REAGENTS]

Tetramethylbenzidine
Alcohol Oxidase (EC 1.1.3.13)
Peroxidase (EC 1.11.1.7)
Other additives

[PRECAUTIONS]

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Oral fluid is not classified as biological hazard unless derived from a dental procedure.
- The used collector and Cup should be discarded according to local regulations.

[ALCOHOL PRECAUTIONS]

Test materials that have been exposed to oral fluid should be treated as potentially infectious. Do not use the Drugs & Alcohol Test after the expiration date marked on the foil package.

[STORAGE AND STABILITY]

Store as packaged in the sealed pouch at 2-30°C.The test is stable through the expiration date printed on the sealed pouch. The test Cup must remain in the sealed pouch until use.
DO NOT FREEZE. Do not use beyond the expiration date.

[ALCOHOL STORAGE AND STABILITY]

The Drugs & Alcohol Test is to be stored at 2-30°C in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, the Oral fluid Alcohol Rapid Test must be brought to room temperature prior to opening the pouch.

[SPECIMEN COLLECTION AND PREPARATION]

The oral fluid specimen should be collected using the collector provided with the kit.
Follow the detailed directions for use below. No other collection cup should be used with this assay. Oral fluid collected at any time of the day may be used.
When testing cards with alcohol storage of oral fluid specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

[MATERIALS]

Materials Provided

- Test cups
- ALC colour chart (when applicable)
- Collectors
- Procedure card
- Package insert

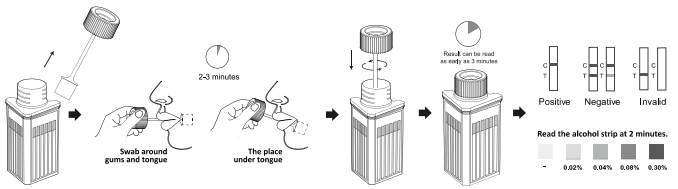
Materials required but not provided

- Timer

[DIRECTIONS FOR USE]

Allow the test cup, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

1. Remove the collection sponge and test cube from the sealed pouch and tear off the packaging around the collection sponge.
2. Insert the sponge end of the saliva collector into the mouth. Actively swab the inside of the mouth and tongue to collect oral fluid for 2-3 minutes (until the sponge becomes fully saturated). Gentle pressing of the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
3. Remove the collector from the mouth. Place saturated oral fluid collector into test cup and screw the collector to press sponge fully to release oral fluid.
4. Place the test cup on a clean and level surface. Remove the peel off label, wait for the flow to appear in test windows and start a timer.
5. If the sample does not migrate in the test cup after 3 minutes, please rotate the cup 4-5 times.
6. Read the test results at 3-10 minutes. If all lines are clearly visible at 3 minutes or sooner, then the test can be interpreted as negative and discarded. If any lines are not visible at 3 minutes, then the test should be re-read at 10 minutes.
7. For the alcohol strip, when applicable, the results should be read at 2 minutes. Compare the colour of the reaction pad with the chart provided separately/on foil pouch to determine the relative oral fluid alcohol level.



[INTERPRETATION OF RESULTS]

(Please refer to the previous illustration)

NEGATIVE:* A coloured line appears in the control region (C) and coloured line appear in the Test region (T). This negative result means that the concentration in the oral fluid sample is below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the coloured lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE:* A coloured line appears in the control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the oral fluid sample is greater than the designated cut-off for a specific drug.

INVALID:* No line appears in the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test. If the result is still invalid, contact your manufacturer.

[ALCOHOL STRIP INTERPRETATION]

Positive: The alcohol test will produce **a colour change** in the presence of oral fluid alcohol. The colour will range from light blue colour at 0.02% relative oral fluid alcohol concentration to a dark blue colour near 0.30% relative oral fluid alcohol concentration. Colour pads are provided within this range to allow an approximation of relative oral fluid alcohol concentration. The test may produce colours that appear to be between adjacent colour pads.

NOTE: The alcohol test is very sensitive to the presence of alcohol. A blue colour that is lighter than the 0.02% colour pad should be interpreted as being positive to the presence of alcohol in oral fluid.

Negative: When the alcohol test shows **no colour change** this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the colour pad has a blue colour before applying the oral fluid sample, do not use the test.

NOTE: A result where the outer edges of the colour pad produces a slight colour but the majority of the pad remains colourless the test should be repeated to ensure complete saturation of the pad with oral fluid. The test is not reusable.

[QUALITY CONTROL]

A procedural control is included in the test. A coloured line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

[LIMITATIONS]

1. The Drugs & Alcohol 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) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.[7]

2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.

3. A negative result may not necessarily indicate a drug-free specimen.
Drugs may be present in the specimen below the cutoff level of the assay.

[ALCOHOL LIMITATIONS]

1. The Drugs & Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapours in the air are sometimes detected by the alcohol test. Alcohol vapours are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorisers, perfumes, and glass cleaners. If the presence of alcohol vapours is suspected, the test should be performed in an area known to be free of vapours.
2. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

[PERFORMANCE CHARACTERISTICS]

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off, ± 25% cut-off and +300% cut-off and tested with the Drugs & Alcohol Test. The results are summarised below:

Drug Concentration Cut-off Range	AMP		THC12		COC		BZO10		KET		OPI/MOP	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	27	3	27	3	26	4	26	4	27	3
Cut-off	15	15	12	18	15	15	19	11	18	12	13	17
+25% Cut-off	7	23	8	22	8	22	6	24	8	22	7	23
+25% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Drugs & Alcohol Test for AMP/ COC/ OPI/MOP/ THC/ BZO/ KET identified positive results at a read time of 5 minutes.

Compound	ng/ml	Compound	ng/ml
Amphetamine (AMP)			
d-Amphetamine	50	p-Hydroxyamphetamine	100
d/l-Amphetamine	100	(+)3,4-Methylenedioxyamphetamine (MDA)	100
ß-Phenylethylamine	25,000	l-Amphetamine	25,000
Tryptamine	12,500	Methoxyphenamine	12,500
Marijuana (THC12)			
11-nor-Δ9 -THC-9 COOH	12	Δ9 -THC 10,000	10,000
Cannabinol	12,500	11-nor-Δ^8-THC-9 COOH	12
Δ8 -THC	6,000		
Cocaine (COC)			
Benzoylecgonine	20		1,500
Cocaine	20		12,500
Cocaethylene	30		
Opiates (OPI)			
Morphine	40	Norcodeine	6,250
Codeine	25	Normorphine	25,000
Ethylmorphine	25	Nalorphine	10,000
Hydromorphine	100	Oxymorphone	25,000
Hydrocodone	100	Thebaine	2,000
Levorphanol	400	Diacetylmorphine (Heroin)	50
Oxycodone	25,000	6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50		
Benzodiazepines (BZO10)			
Alprazolam	10	Flunitrazepam	10
a-hydroxyalprazolam	80	(±) Lorazepam	150
Bromazepam	50	RS-Lorazepamglucuronide	10
Chlordiazepoxide	50	Midazolam	300
Clobazam	10	Nitrazepam	10
Clonazepam	25	Norchlordiazepoxide	10
Clorazepatedipotass	25	Nordiazepam	50
Delorazepam	50	Oxazepam	10
Desalkylflurazepam	10	Temazepam	10
Diazepam	800	Triazolam	1500
Estazolam	300		
Ketamine(KET)			
Ketamine 50	50	Mephentermine 1250	1250
Tetrahydrozoline	20	Phencyclidine	625
Benzphetamine	1250	(1R, 2S) - (-)Ephedrine	5000
d-Methamphetamine	1250	Promazine	1250
(+)Chlorpheniramine	1250	4-Hydroxyphencyclidine	2500
l-Methamphetamine	2500	Promethazine	1250
Clonidine	5000	Levorphanol	2500
Methoxyphenamine	625	Thioridazine	2500
Disopyramide	625	MDE	2500
d-Norpropoxyphene	625	Meperidine	1250
EDDP	2500	Dextromethorphan	75
Pentazocine	1250	(+)3,4-Methylendioxymethamphetamine (MDMA)	5000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Drugs & Alcohol test when tested with at concentrations up to 100 µg/mL.

Acetaminophen	d/l-Chloropheniramine	Sulfamethazine
N-Acetylprocainamide	Chloroquine	Tetracycline
Aminopyrine	Clonidine	Tetrahydrocortisone 3 (β-D-glucuronide)
Ampicillin	l-Cotinine	Thioridazine
Apomorphine	Deoxycorticosterone	Tolbutamide
Atropine	Diclofenac	Trifluoperazine
Benzoic acid	Digoxin	d/l-Tryptophan
d/l-Brompheniramine	l -Ψ-Ephedrine	Uric acid
Chloral-hydrate	Estrone-3-sulfate	Ketoprofen
Chlorothiazide	l(–)-Epinephrine	Loperamide
Chlorpromazine	Fenoprofen	Meprobamate
Cholesterol	Gentisic acid	Nalidixic acid
Cortisone	Hydralazine	Niacinamide
Creatinine	Hydrocortisone	Norethindrone
Dextromethorphan	p-Hydroxytyramine	Noscapine
Diflunisal	Iproniazid	Oxalic acid
Diphenhydramine	Isoxsuprine	Oxymetazoline
β-Estradiol	Labetalol	Penicillin-G
Ethyl-p-aminobenzoate	Meperidine	Perphenazine
Erythromycin	Methylphenidate	Trans-2-phenylcyclopropylamine hydrochloride
Furosemide	Naproxen	Prednisolone
Haemoglobin	Nifedipine	d/l-Propranolol
Hydrochlorothiazide	d-Norpropoxyphene	d-Pseudoephedrine
o-Hydroxyhippuric acid	d/l-Octopamine	Quinine
Ibuprofen	Oxolinic acid	Ranitidine
d/l-Isoproterenol	Papaverine	Serotonin
Acetophenetidin	Pentazocine hydrochloride	Sulindac
Acetylsalicylic acid	Phenelzine	Tetrahydrocortisone 3-acetate
Amoxicillin	Phenylpropanolamine	Thiamine
l-Ascorbic acid	Prednisone	d/l-Tyrosine
Aspartame	d-Propoxyphene	Triamterene
Benzilic acid	Quinacrine	Trimethoprim
Benzphetamine	Quindine	Tyramine
Caffeine	Salicylic acid	Verapamil
Chloramphenicol	Zomepirac	

[ALCOHOL PERFORMANCE CHARACTERISTICS]

The detection limit on the alcohol test is from 0.02% to 0.30% for approximate relative blood alcohol level. The cut-off level of the alcohol test can vary based on local regulations and laws. Test results can be compared to reference levels with colour chart on the foil package.

[ALCOHOL ASSAY SPECIFICITY]

The alcohol test will react with methyl, ethyl and allyl alcohols[8].

[ALCOHOL INTERFERING SUBSTANCES]

The following substances may interfere with the Oral fluid Alcohol Rapid Test when using samples other than oral fluid. The named substances do not normally appear in sufficient quantities in oral fluid to interfere with the test.

A. Agents which enhance colour development

• Peroxidases

• Strong oxidizers

B. Agents which inhibit colour development

• Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.

• Bilirubin

• L-dopa

• L-methyldopa

• Methampyrone

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Index of Symbols

	Caution		Tests per kit		Authorised Representative
	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Manufacturer

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Number: 146051600
Effective date: 2019-05-24