Oral Fluid Drug Test Package Insert

For Forensic Use Only.
For in vitro diagnostic use.

INTENDED USE

The Oral Fluid Drug Test is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and metabolites in human oral fluid of following drugs without the need of instruments. Package insert for testing of any combination of the following drugs:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	Amphetamine	50
Barbiturates (BAR)	Secobarbital	50
Buprenorphine (BUP)	Buprenorphine	5
Benzodiazepines (BZO)	Oxazepam	50
Cocaine (COC)	Benzoylecgonine	20
Fentanyl (FYL)	Norfentanyl	20
Synthetic Cannabinoid (K2)	JWH-073/JWH-018	20
MDMA	3,4-Methylenedioxymethamphetamine	50
Methamphetamine (MET)	d-Methamphetamine	50
Morphine (MOP)/ Opiate (OPI)	Morphine	40
Methadone (MTD)	Methadone	30
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene（PPX）	Propoxyphene	25
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	40
Alcohol (ALC)	Alcohol	0.02%

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.
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) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

PRINCIPLE

The Oral Fluid Drug Test is an immunoassay based on the principle of competitive binding. Drugs which may be present in the saliva specimen compete against their respective drug conjugate for binding sites on their specific antibody.
During testing, a saliva specimen migrates upward by capillary action. A drug, if present in the saliva specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.
A drug-positive saliva specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative saliva specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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.
The Alcohol (ALC) Rapid Test consists of a plastic strip with a reaction pad. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

COMPOSITION

- Each test kit contains Oral Fluid Drug Test, alcohol color chart (when applicable) and package insert.
- Materials required but not provided: timer.

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 15-30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note: All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.

WARNINGS, PRECAUTIONS AND LIMITATIONS

- For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to local regulations.
- The Multi-Drugs Rapid Test Device provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the saliva specimen may cause erroneous results.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in oral fluid.
- A negative result may not necessarily indicate drug-free saliva. Negative results can be obtained when drug is present but below the cut-off level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

The Limitations of Alcohol Test

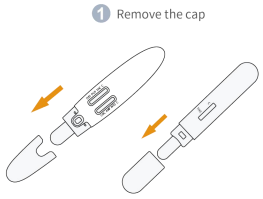
- Failure to wait 15 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
- The Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol Rapid Test. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
- Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

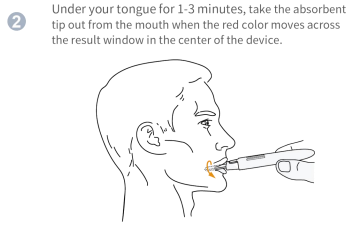
SPECIMEN STORAGE

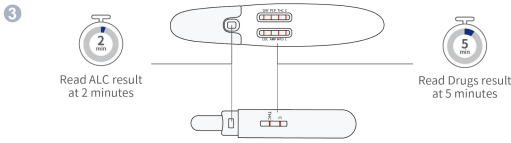
Saliva specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

SPECIMEN COLLECTION AND TEST PROCEDURE

The test subject should not eat, drink or smoke for at least 10 minutes before the test. Refrigerated tests and saliva samples should be brought to room temperature (15-30°C) prior to testing. For saliva testing, donor must not place anything in the mouth including food, drink, gum, or tobacco products for at least 15 minutes prior to sample collection.
1.Before testing, read the instructions thoroughly and perform the operations as directed. The test card should also be warmed up to room temperature.
2.Open the foil pouch, take out the test device and remove the cap of the test device at the bottom to expose the absorbent tip.
3.Place the absorbent tip horizontally into the mouth, then swab the inside of the mouth and tongue to collect oral fluid. The absorbent pad should be touching tongue or under tongue.
4.Take the absorbent tip out from the mouth when the red color moves across the result window in the center of the device.
Note: Make sure the test device is horizontal to prevent flooding. When sampling, gently hold it in mouth and let oral fluid naturally adsorb on the absorbent pad.
5.Return the cap of the test device and place it on a clean surface horizontally and start the timer.
6.**Read the alcohol test result at 2 minutes, compare the reactive pad with the provided color chart. Do not read after 3 minutes.**
7.**Read the drug test results at 5 minutes. Do not read after 10 minutes.**







INTERPRETATION OF TEST RESULTS

NEGATIVE RESULT

A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the specimen is below the designated cut-off level for that specific drug.
***Note:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint colored line.*

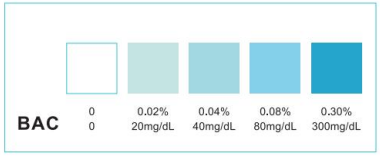
PRELIMINARY POSITIVE RESULT

A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the specimen exceeds the designated cut-off for that specific drug.

INVALID RESULTS

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

The Result for Alcohol test:



Positive: A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks.

Negative: No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.

Invalid: The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with the specimen. If the problem persists, do not continue the test and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE

1. Accuracy
The clinical performance of the Drug rapid tests were specified by using saliva specimens for which the drug concentration had been determined. All Drug rapid tests showed a good performance. The following table gives a summary of the study results. Values were rounded:

Parameter	Sensitivity	Specificity	PPV*	NPV**

AMP 50	>95%	>95%	>95%	>95%
BAR 50	>95%	>95%	>95%	>95%
BUP 5	>95%	>95%	>95%	>95%
BZO 50	>95%	>95%	>95%	>95%
COC 20	>95%	>95%	>95%	>95%
FYL 20	>95%	>95%	>95%	>95%
K2 20	>95%	>95%	>95%	>95%
MDMA 50	>95%	>95%	>95%	>95%
MET 50	>95%	>95%	>95%	>95%
MOP/OPI 40	>95%	>95%	>95%	>95%
MTD 30	>95%	>95%	>95%	>95%
OXY 20	>95%	>95%	>95%	>95%
PCP 10	>95%	>95%	>95%	>95%
PPX 25	>95%	>95%	>95%	>95%
THC 40	>95%	>95%	>95%	>95%

2. Analytical Sensitivity

A drug-free saliva pool was spiked with drugs to the concentrations at ±50% cut-off, cutoff and±25% cut-off. The results are summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BUP		BZO		COC		FYL		K2	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	29	1	28	2	30	0	29	1	28	2	30	0
Cut-off	30	18	12	17	13	11	19	14	16	12	18	14	16	13	17
+25% Cut-off	30	2	28	8	22	8	22	4	26	2	28	5	25	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MDMA		MET		MOP/OPI		MTD		OXY		PCP		PPX		THC	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	28	2	30	0	28	2	28	2	28	2	27	3	28	2
Cut-off	30	14	16	13	17	15	15	14	16	15	15	16	14	14	16	16	14
+25% Cut-off	30	4	26	3	27	5	25	2	28	4	26	7	23	6	24	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

3. Analytical Specificity

Compounds	Con.ng/mL	Compounds	Con.ng/mL
AMPHETAMINE			
d-Amphetamine	50	d-MDA	50
d,l-Amphetamine	100	Tyramine	10,000
r-Amphetamine	1,000		
BARBITURATES			
Secobarbital	50	Butalbital	100
Phenobarbital	400	Barbital	500
Amobarbital	400		
BUPRENORPHINE			
Buprenorphine	5	Norbuprenorphine	25
Buprenorphine-3-β-D-glucuronide			5
Norbuprenorphine-3-β-D-glucuronide			25
BENZODIAZEPINES			
Oxazepam	50	Nitrazepam	50
Alprazolam	30	Nordiazepam	80
Chlordiazepoxide	20	Temazepam	60
Clobazam	80	Triazolam	10
Diazepam	80	Estazolam	80
Flurazepam	60	Desalkyflurazepam	80
Lorazepam	360	Flunitrazepam	300
Midazolam	2000	α-Hydroxyalprazolam	20
Clonazepam	500		
COCAINE			
Benzoylecgonine	20	Ecgonine	6,400
Cocaine	24	Ecgonine methyl ester	29,000
FENTANYL			
Norfentanyl	20	Fentanyl	200
K2			
JWH 073 4-butanoic acid	20	JWH 018 5-pentanoic acid	20
JWH-073 4-Hydroxybutyl metabolite			80
JWH-018 N-(4-hydroxypentyl) metabolite			80
JWH-018 5-Hydroxypentyl metabolite			100
JWH-018 (Spice Cannabinoid)			32,000
MDMA			
3,4-Methylenedioxymethamphetamine			50
d-Methamphetamine			10,000
3,4-Methylenedioxyethylamphetamine (MDEA)			30
3,4-Methylenedioxyamphetamine (MDA)			180
d,l-Methamphetamine			6,250
l-Methamphetamine			6,250
METHAMPHETAMINE			
d-Methamphetamine	50	l-Methamphetamine	7000
d,l-Methamphetamine	125	l-Amphetamine	＞100,000
3,4-Methylenedioxymethamphetamine（MDMA）			650
3,4-Methylenedioxyamphetamine (MDA)			66,000
3,4-Methylenedioxyethylamphetamine (MDEA)			600
MORPHINE			
Morphine	40	Heroin	80
6-Acetylmorphine	50	Hydrocodone	1300
Codeine	25	Hydromorphone	400
Dihydrocodeine	40	Oxycodone	80,000
Ethyl morphine	40	Morphine-3-β-D-glucuronide	200
METHADONE			
Methadone	30	Doxylamine	100,000
Phencyclidine			＞100,000
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine (EDDP)			＞100,000
OXYCODONE			
Oxycodone	20	Oxymorphone	1,000
Hydrocodone	5,000	Hydromorphone	8,000
PHENCYCLIDINE			
Phencyclidine	10	4-Hydroxyphencyclidine	5,000
PROPOXYPHENE			
Propoxyphene			25
MARIJUANA			
11-nor-Δ^9-THC-9 COOH	40	Δ^8–THC	10,500
Cannabinol	>100,000	Δ^9–THC	6,640

INTERFERENCE

A study was conducted to determine the interference of the test with compounds in either drug-free saliva or positive saliva. The following compounds show no interference when tested with the Drugs of Abuse Rapid Test at a concentration of 100 μg/mL.

NON INTERFERENCE

Acetophenetidin	Cortisone	Isoxsuprine	d-Pseudoephedrine
N-Acetylprocainamide	l-Cotinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Creatinine	Labetalol	Quinine
Aminopyrine	Deoxycorticosterone	Loperamide	Salicylic acid
Amoxicillin	Dextromethorphan	Meprobamate	Serotonin
Ampicillin	Diclofenac	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Diflunisal	Methylphenidate	Sulindac
Apomorphine	Digoxin	Nalidixic acid	Tetracycline
Aspartame	Diphenhydramine	Naproxen	Tetrahydrocortisone,
Atropine	Ethyl-p-aminobenzoate	Niacinamide	3-Acetate
Benzilic acid	β-Estradiol	Nifedipine	Tetrahydrocortisone
Benzoic acid	Estrone-3-sulfate	Norethindrone	Tetrahydrozoline
Bilirubin	Erythromycin	Noscapine	Thiamine
d,l-Brompheniramine	Fenoprofen	d,l-Octopamine	Thioridazine
Caffeine	Furosemide	Oxalic acid	d,l-Tyrosine
Cannabidiol	Gentisic acid	Oxolinic acid	Tolbutamide
Chloral hydrate	Hemoglobin	Oxymetazoline	Triamterene
Chloramphenicol	Hydralazine	Papaverine	Trifluoperazine
Chlorothiazide	Hydrochlorothiazide	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	Hydrocortisone	Perphenazine	d,l-Tryptophan
Chlorpromazine	o-Hydroxyhippuric acid	Phenelzine	Uric acid
Cholesterol	3-Hydroxytyramine	Prednisone	Verapamil
Clonidine	d,l-Isoproterenol	d,l-Propanolol	Zomepirac

REFERENCES

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Multi-Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse

Number: 1624288702
Effective date: 2025-12-10