Multi-Drugs Saliva Rapid Test Cube Package Insert

For medical and other professional *in vitro* diagnostic use only

INTENDED USE & SUMMARY

The Multi-Drugs Saliva Rapid Test Cube 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	Cut-off (ng/mL)
Amphetamine (AMP)	50
Barbiturates (BAR)	50
Buprenorphine (BUP)	10/5
Benzodiazepines (BZO)	50/30
Cocaine (COC)	50/20
Fentanyl (FYL)	50/20/10
K2	25
Ketamine (KET)	50
Methylenedioxymethamphetamine(MDMA)	50
Methylenedioxypyrovalerone (MDPV)	300
Marijuana (THC)	50/20
Methamphetamine (MET)	50
Methadone metabolite (EDDP)	20
Methadone (MTD)	30
Opiate (OPI) / Morphine (MOP)	40/20
Oxycodone (OXY)	20
Phencyclidine (PCP)	10
Tramadol (TRA)	30
Tricyclic Antidepressants (TCA)	100
Alcohol (ACL)	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 Multi-Drugs Saliva Rapid Test Cube 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.

Saliva Alcohol 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 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 test cube, saliva collector 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 professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cube 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 cube should be discarded according to local regulations.
- The Multi-Drugs Saliva Rapid Test Cube 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 Saliva Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol 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.

Sample Collection

The oral fluid should be collected using the collector provided with the kit. Follow the detailed "Test procedure" below. No other collection device should be used with this test. Oral fluid collected at any time of the day may be used.

1. Remove the saliva collector (collection sponge) and the Saliva Cube Test from the foil pouch. Relax the mouth and insert the collection sponge into the mouth. Start Timer.
2. The collection sponge must be in horizontal position throughout the collection process. Using a circular motion, gently swab both cheeks 5-10 times, gums 5-10 times, and surface of tongue 5-10 times, actively swab the inside the mouth, top of tongue, and between cheek and gum until the volume indicator is completely covered with a **Red "OK" (usually about 2-4 minutes)**. Lightly pressing the sponge between the tongue and teeth will help the sponge absorb the saliva. Once saturated, the sponge should contain no hardened areas.

Important: Do not bite, suck, or chew on the collection swab. It is critical that the collection sponge is held horizontally during collection otherwise there will be insufficient saliva collected although the indicator turns Red. During collection of the oral fluid, relax the mouth while swabbing the tongue and check as this will aid in the collection of the oral fluid.

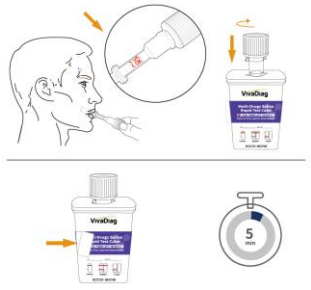
Please note: After Sample is collected, carry out testing within 7 minutes, even if the volume/saturation indicator has not yet changed.

Sample Test

1. Remove the Saliva Cube from sealed pouch and place it upright on a clean, flat surface. Gently and slowly Insert the saliva collector into the saliva cube with the buckle on the top of the saliva collector aligned with the catch of the saliva cube, press to the bottom, and turn clockwise until you hear a click.
2. Stand the test cube upright on a flat surface and begin the timer. Ensure that the cube remains upright for the duration of the test.
3. Subject dates and adds initials to the label on the cube.
4. Remove the peel-off label.
5. **If an alcohol test is available**, read the results of the Alcohol tests at **3-5 minutes.**
6. Read the results of the Drug tests at **5-10 minutes.**

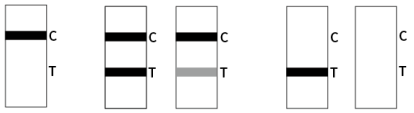
Notes and Troubleshooting

- Invalid results may occur, if the strips do not wick, or the oral fluid is too thick or viscous to run, and the oral fluid tends to form air bubbles which sit at the bottom of the strip and prevent the strip from running.
- If strips do not appear to flow, gently tap the cube on the table or counter surface and gently move the cube back and forth several times, allowing capillary action to begin, thus initiating the test.
- The indicator has not turned Red after 5 minutes: Some donors may have a dry mouth. Rotate the swab in a circular motion while swabbing each area of the oral cavity until the saturation indicator activates and turns **Red "OK"**.



INTERPRETATION OF TEST RESULTS

DRUG TEST:



Positive **Negative** **Invalid**

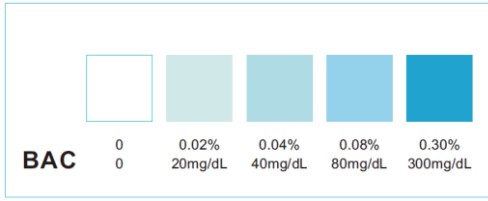
Positive: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the specimen exceeds the designated cut-off for that specific drug.

Negative: Two distinct colored lines appear. 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.*

Invalid: 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.

ALCOHOL TEST:



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.

Positive: A color change appears on the reaction pad. The BAC will range from 0.02% to 0.30%, with the color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the pouch.

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 specimens were analyzed by GC-MS and the Multi-Drugs Saliva Rapid Test Cube. Saliva samples taken from volunteers claiming to be non-users were examined under both tests. The results were >95% in agreement with GC/MS.

2. Analytical Sensitivity

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

Drug Conc. (Cut-off range)	n	AMP		BAR		BUP		BUP5		BZO 50		BZO 30	
		-	+	-	+	-	+	-	+	-	+	-	+
0%	30	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
-25% Cut-off	30	30	0	29	1	29	1	29	1	30	0	29	1
Cut-off	30	12	18	14	16	12	18	12	18	12	18	14	16
+25% Cut-off	30	2	28	8	22	4	26	2	28	4	26	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	COC 50		COC 20		FYL		FYL 20		FYL 10		K2	
		-	+	-	+	-	+	-	+	-	+	-	+
0%	30	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
-25% Cut-off	30	29	1	28	2	28	2	29	1	28	2	29	1
Cut-off	30	17	13	15	15	19	11	18	12	18	12	17	13
+25% Cut-off	30	2	28	2	28	6	24	3	27	4	26	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	KET		MDMA		MDPV		THC		THC 20		MET	
		-	+	-	+	-	+	-	+	-	+	-	+
0%	30	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
-25% Cut-off	30	28	2	28	2	24	6	24	6	24	6	28	2
Cut-off	30	19	11	17	13	15	15	14	16	15	15	14	16
+25% Cut-off	30	6	24	4	26	5	25	5	25	3	27	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	EDDP		MTD		OPI		OPI 20		OXY	
		-	+	-	+	-	+	-	+	-	+
0%	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	28	2	28	2	27	3	28	2
Cut-off	30	15	15	16	14	14	16	14	16	14	16
+25% Cut-off	30	5	25	2	28	9	21	2	28	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	PCP		TRA		TCA	
		-	+	-	+	-	+
0%	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0

-25% Cut-off	30	28	2	28	2	28	2
Cut-off	30	14	16	17	13	18	12
+25% Cut-off	30	9	21	7	23	6	24
+50% Cut-off	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	Amobarbital	400
Butalbital	100	Barbital	500
Phenobarbital	400		
Buprenorphine			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine-3-β-D-glucuronide	10	Norbuprenorphine-3-β-D-gluc	50
Buprenorphine			
Buprenorphine	5	Norbuprenorphine	25
Buprenorphine-3-β-D-glucuronide	5	Norbuprenorphine-3-β-D-gluc	25
BENZODIAZEPINES 50			
Oxazepam	50	Nordiazepam	300
Alprazolam	20,000	Temazepam	25
Chlordiazepoxide	8,000	Triazolam	＞100,000
Clobazam	750	Estazolam	250
Diazepam	90	Desalkyflurazepam	1,000
Flurazepam	＞100,000	Flunitrazepam	＞100,000
Lorazepam	6,500	Midazolam	80,000
Nitrazepam	16,500		
BENZODIAZEPINES 10			
Oxazepam	30	Nordiazepam	180
Alprazolam	12,000	Temazepam	15
Chlordiazepoxide	4,800	Triazolam	60,000
Clobazam	450	Estazolam	150
Diazepam	54	Desalkyflurazepam	600
Flurazepam	60,000	Flunitrazepam	60,000
Lorazepam	3,900	Midazolam	48,000
Nitrazepam			
COCAINE 50			
Benzoylecgonine	50	Ecgonine	16,000
Cocaine	60	Ecgonine methyl ester	72,500
COCAINE 20			
Benzoylecgonine	20	Ecgonine	6,400
Cocaine	24	Ecgonine methyl ester	29,000
FENTANYL 50			
Fentanyl	50	Norfentanyl	50
FENTANYL 20			
Fentanyl	20	Norfentanyl	20
FENTANYL 10			
Fentanyl	10	Norfentanyl	10
SPC/K2			
JWH 073 4-butanoic acid	25	JWH 018 5-pentanoic acid	25
JWH-0734-Hydroxybutyl	100	JWH-0185-Hydroxypentyl	125
JWH-018N-(4-hydroxypentyl)	100	JWH-018 (Spice Cannabinoid)	40,000
KETAMINE			
Ketamine	50	Norketamine	50
METHYLENEDIOXYMETHAMPHETAMINE			
3,4-Methylenedioxymethamphetamine（MDMA）			50
3,4-Methylenedioxyamphetamine (MDA)			6,250
3,4-Methylenedioxyethylamphetamine (MDEA)			20
Methamphetamine			1,125
l-methamphetamine			2,000
METHYLENEDIOXYPYROVALERONE			
3,4-Methylenedioxypyrovalerone			300
METHAMPHETAMINE			
Methamphetamine	50	MDEA	400
MDMA	100	d,l-Ephedrine	20,000
d-MDA	30,000	1R, 2S, l-Ephedrine	＞100,000
d,l-Methamphetamine	60	R(-)-Amphetamine	＞100,000
l-Methamphetamine	2500		
METHADONE METABOLITE			
Methadone metabolite	20	Phencyclidine	20,000
Meperidine	20,000	Promazine	10,000
Methadone	20,000	Promethazine	5,000
Norfentanyl	20,000	Prothipendyl	10,000
Prozine	2,500		
METHADONE			
Methadone	30	Doxylamine	100,000
MARIJUANA			
Δ^9-Tetrahydrocannabinol	50	11-nor-Δ9 -THC-9 COOH	15
Δ^8-Tetrahydrocannabinol	75	Cannabinol	＞10,000
MARIJUANA			
Δ^9-Tetrahydrocannabinol	20	11-nor-Δ9 -THC-9 COOH	6
Δ^8-Tetrahydrocannabinol	30	Cannabinol	4,000
OPIATES 40			
Morphine	40	Heroin	80
6-Acetylmorphine	48	Hydrocodone	1,280
Codeine	24	Hydromorphone	400
Dihydrocodeine	40	Oxycodone	80,000
Ethyl morphine	40	Morphine-3-β-D-glucuronide	200
OPIATES 20			
Morphine	20	Heroin	40
6-Acetylmorphine	24	Hydrocodone	640
Codeine	12	Hydromorphone	200
Dihydrocodeine	20	Oxycodone	40,000
Ethyl morphine	20	Morphine-3-β-D-glucuronide	100
OXYCODONE			
Oxycodone	20	Hydrocodone	5,000
Oxymorphone	1,000	Hydromorphone	8,000
TRAMADOL			
Tramadol			30
TRICYCLIC ANTIDEPRESSANTS			
Nortriptyline			100

INTERFERENCE

A study was conducted to determine the interference of the test with compounds in either drug-free saliva or Amphetamine,Benzoylecgonine,Cocaine,Ketamine,Marijuana,Methadone,3,4-Methylenedioxy-Metamphetamine, d-Methamphetamine, Morphine positive saliva. The following compounds show no interference when tested with the Multi-Drugs Saliva Rapid Test Cube 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
EC REP	Authorized Representative				

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CE IVD

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