

Drug **ALERT**

MARIJUANA THC

SALIVA Rapid SCREENING Test

A one step drug screen test.

A rapid one step screening test for the detection of Marijuana (THC) in saliva.

For in vitro diagnostic use only.

Drug Alert Kits are also available as:-

◆ **A urine multi test for 6 of the most common street drugs:**

- Marijuana THC
- Cocaine COC
- Opiates OPI (*Opium & Heroin*)
- Amphetamines AMP (*Speed*)
- Methamphetamine MET (*Crystal*)
- Methylenedioxymethamphetamine MDMA (*Ecstasy*)

◆ **A urine multi test for 10 of the most common street & prescription drugs:**

Street Drugs - see above list

Prescription Drugs

- Tricyclic TCA (*Antidepressants*)
- Barbiturates BAR
- Benzodiazepine BZO
- Methadone MTD

◆ **A urine single test kit for Marijuana THC**

INTENDED USE

The Drug Alert marijuana/hashish (THC) saliva screening test is a one step rapid immunoassay for the detection of THC in human oral fluid at a cut-off concentration of 12 ng/mL.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrophotometry (GC/MS) or high performance liquid chromatography 9HPLC0 are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

MARIJUANA THC

THC (Δ^9 -tetrahydrocannabinol) is the primary active ingredient in cannabinoids (Marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. Users may also experience transient episodes of confusion and anxiety. Long term heavy use may be associated with behavioral disorders. The peak effect of Marijuana administered by smoking usually occurs in 20-30 minutes and the duration is between approximately 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for between 3-10 days after smoking.

PRINCIPLES OF THE PROCEDURE

The test is a one-step lateral flow chromatographic immunoassay based on the principle of competition for limited antibody binding sites between the drug in the sample and a drug-protein conjugate immobilized on a porous membrane support.

During testing, oral fluid migrates toward the membrane by capillary action, mobilizing colored antibody conjugates in the porous support. The fluid containing the antibody conjugates then moves along the membrane to the test area.

In the absence of drug or if drug concentrations are below the cutoff limit (12ng/mL) in the oral fluid, the coloured conjugates attach to the drug antigen immobilized in the test line region, forming a coloured band (T line). If drug is present in the oral fluid, the drug compete with the coloured antibody conjugates for the limited antibody binding sites. If the drug concentration is at or above the cutoff limit, the drug will saturate all the binding sites of the antibody, preventing the attachment of the coloured conjugates to the antigen in the test line area of the membrane. Therefore no coloured line will form.

The control line (C line) serves as an internal quality control of the system. It should always appear as a coloured band regardless of the presence of the drug.

MATERIAL SUPPLIED

- 1 x Individually pouched test device.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

PRECAUTIONS

- The instructions must be followed exactly to obtain accurate results.
- Do not open the sealed pouch until ready to conduct the assay.
- Do not use expired devices.
- Do not moisten nitrocellulose membrane with samples.
- Dispose of used device according to local regulations.

STORAGE AND STABILITY

- Store the product in the sealed pouch at room temperature, 15-30° (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.
- Do not freeze and/or expose this kit to temperatures over 30°C (86°F).

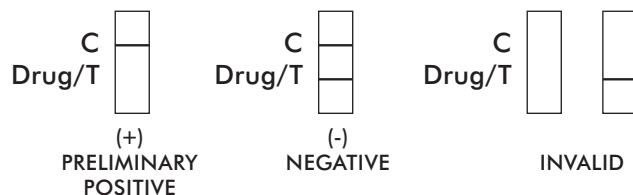
SPECIMEN COLLECTION AND TESTING

The test device must be equilibrated to room temperature before testing.

1. Bring the sealed pouch to room temperature before opening. Remove the test device from the pouch and use it as soon as possible
2. Remove cap and insert the collection pad end of the device into the subject's mouth, wiping the pad in the subject's mouth for about 1-3 minutes until the collection pad is completely saturated
Keep the opposite end of the device angled downward to ensure good flow, and do not pull on or chew the collection pad.
3. When colour appears in the result window remove the device from the subject's mouth and replace the cap onto the collection pad end of the device. Lay the device on a flat surface.
4. Start timing once the C line is visible in the test window. Read results 5-7 minutes after the C line appears.

INTERPRETATION OF RESULTS

IMPORTANT: Do not read test results after seven (7) minutes following appearance of the C line. The T line should always be interpreted independently of the C line. Do not compare colour intensity of one test line to another.



PRELIMINARY POSITIVE:

If a coloured line appears in the control line region (C), but there is not line in the test line region (T) the result indicates a positive result for the drug.

Note: Samples with preliminary positive results should be confirmed with a more specific method before positive determinations are made.

NEGATIVE:

A coloured line in the control line region (C) and another line in the test line region (T) indicate that the drug is not present, or the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

Note: A very faint T line should be considered negative.

INVALID:

If no C line develops, the result is invalid. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device.

QUALITY CONTROL

Built-In Control Features:

This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If no C line forms, the test is considered invalid. Review the procedure and repeat testing with a new device.

LIMITATIONS

- This kit is for professional *in vitro* diagnostic use only.
- Results obtained by this device provide only a preliminary, qualitative analytical test result. A more specific chemical method must be used to obtain a confirmed analytical result.
- This product is designed for testing human oral fluid only.
- A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the test.

EXPECTED VALUES

This test is capable of detecting a specific drug and/or drug metabolite in human oral fluid at or above its specific cutoff concentration indicated in the Intended Use Section.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study was performed at an academy of science. Ninety (90) samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested with the drug of abuse saliva device and compared to HPLC/MS results. The test results are grouped into: below 50% cutoff (Negative), between 50% cutoff and cutoff, between cutoff and 150% cutoff and above 150% cutoff (Positive). Seven (7) discrepancies were observed at the level between cutoff and 150% cutoff.

Overall, this device agrees with the results from the selected analytical method at more than 95% for each analyte. The test results are tabulated as follows:

THC		Cutoff: 12 ng/mL		Total	Agreement
		Positive	Negative		
HPLC/MS (ng/mL)	Negative (<50%)	0	30	30	100%
	50% - cutoff	0	10	10	100%
	cutoff - 150%	8	2*	10	80%
	Positive (>150%)	40	0	40	100%
Total		48	42	90	97.7%

Reproducibility:

The reproducibility of the test was determined by replicate assays of three product development lots with four levels of samples: negative, 50% cutoff, 150% cutoff, positive. A total of two hundred and sixteen devices were tested for three consecutive days, six replicates per day. The results indicate over 97% agreement with the replicates within each lot and for inter-lot variation.

Cross Reactivity:

The cross reactivity of the test was evaluated by spiking drug free samples with structurally related compounds. Compounds producing positive responses are listed below:

Drug	Compound	Concentration (ng/mL.)
THC	(-)-11-nor- Δ^9 -THC-9-COOH	12
	11-Hydroxy- Δ^9 -THC	300
	11-nor- Δ^9 -THC-9-COOH	12

Interference:

The following commonly used analytes were evaluated in both drug free saliva pools and in pools spiked with the cutoff level of each substance. The tables below list the concentrations at which the substances and analytes do not interfere with the test results:

Substance	Concentration	Substance	Concentration
Acetaminophen	100 ng/mL	Isoxsuprine	100 ng/mL
Acetylsalicylic acid	100 ng/mL	MBDB	100 ng/mL
Amitriptyline	100 ng/mL	MDEA	10 ng/mL
Amobarbitat	100 ng/mL	MDMA	1 ng/mL
Ampicillin	100 ng/mL	Meperidine	1 ng/mL
Aspirin	100 ng/mL	Methadone	1,000 ng/mL
Benzoic acid	100 ng/mL	Methadol	100 ng/mL
Buprenorphine	100 ng/mL	Methanol	100 ng/mL
Butabarbital	100 ng/mL	Penicillin-G	100 ng/mL
Butalbital	100 ng/mL	Phenothiazine	100 ng/mL
Caffeine	100 ng/mL	Salicylic acid	100 ng/mL
Cortisone	100 ng/mL	EDDP	100 ng/mL
Ethanol	100 ng/mL	Gentisic acid	100 ng/mL
Hydroxybutyric acid	1,000 ng/mL	Ecgonine methyl ester	10 ng/mL
Imipramine	1 ng/mL		

Substance	Concentration	Substance	Concentration
Albumin	2,000 ng/mL	Hemoglobin	100 ng/mL
Bilirubin	100 ng/mL	Uric acid	100 ng/mL
Creatine	100 ng/mL	Vitamin C	100 ng/mL
Glucose	200 ng/mL	(l-Ascorbic acid)	

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Unit 1, 47-53 Moxon Road, Punchbowl NSW 2196 Australia