

Instant-View™ Marijuana/THC Urine Test (Cassette)

ONE STEP ASSAY RAPID VISUAL RESULTS FOR QUALITATIVE IN VITRO DIAGNOSTIC USE

INTENDED USE

This device is a qualitative immunoassay intended to be used to detect 11-nor- Δ -9 THC-9-carboxylic acid (THC), a major metabolite of marijuana, in human urine at a cutoff level of 50 ng/ml. It is intended for health care professional use only.

Instant-View™ Marijuana (THC) Urine Test 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 Spectrophotometry (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.¹

SUMMARY AND EXPLANATION OF THE TEST

Tetrahydrocannabinols (THC, Δ -9-THC, Δ -1-THC) are the most active of the principle constituents, as well as the major metabolites, of cannabinoids such as marijuana and hashish. Cannabinoids have been used as central nervous system depressants. Overdose and extended usage of cannabinoids may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. The detection of THC in human urine is widely used to evaluate the abuse of cannabinoids.^{2,3,4}

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip in the device includes 1) a burgundy-colored conjugate pad containing mixture of monoclonal anti-THC antibodies conjugated to colloidal gold, and 2) nitrocellulose membrane containing a test region (T line) and a control region (C line). The T line is coated with THC-BTG antigen, and the C line is coated with goat anti-mouse IgG antibody.

This test is a competitive binding immunoassay. The THC in the urine specimen competes with the THC-BTG antigen coated on the nitrocellulose membrane for the limited binding sites of the anti-THC antibody in the conjugate pad.

When proper amount of urine specimen is placed in the sample well of the device, the urine specimen migrates by capillary action through the test strip. If the THC level in the specimen is below the cutoff level of 50 ng/ml, the burgundy-colored anti-THC antibody conjugate will bind to the THC-BTG antigens coated on the nitrocellulose membrane (the T line), and form a burgundy line, indicating a negative result.

If THC is present in the urine specimen at a cutoff level of 50 ng/ml or higher, it will bind with the anti-THC conjugate so that no burgundy line develops in the T region during testing, indicating a positive result.

The C line is coated with goat anti-mouse antibody, which should bind to the gold-antibody conjugate and form a burgundy colored line regardless of the presence of THC.

REAGENTS AND MATERIALS SUPPLIED

- 25 test devices, each sealed in a pouch with a dropper pipette and a desiccant.
- One package insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer

STORAGE AND STABILITY

Store the kit at room temperature 59-86°F (15-30°C). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch containing desiccant.

Do not freeze the kit and/or expose the kit to the temperature over 30°C.

SPECIMEN COLLECTION

- Each urine specimen must be collected in a clean container.

- Specimens may be kept at room temperature for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix specimens.

PRECAUTION

- The instructions must be followed to obtain accurate results.
- Do not open the sealed pouch, unless ready to operate the assay.
- Do not use expired devices.
- Dispose of all specimens and used assay materials in a proper biohazard container.

ASSAY PROCEDURE

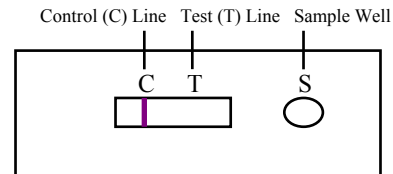
- Refrigerated specimens or other materials **must be equilibrated to room temperature before testing.**
- Remove the test device from its pouch and place it on a flat surface. Label the device with specimen identification.
- Holding the dropper vertically, add four drops (about 160 μ l) of the specimen to the sample well marked as "S" on the device.
Note: If migration is not observed in 30 seconds in the results window, add one or two extra drops of urine specimen.
- Read the test result between four (4) to seven (7) minutes after adding the specimen.

IMPORTANT: Do not read test results after seven (7) minutes.

INTERPRETATION OF RESULTS

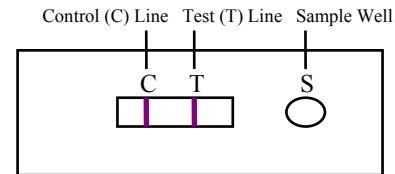
POSITIVE: If only the C line appears, the THC level in the sample is at a cutoff level of 50 ng/ml or higher.

Samples with positive results should be confirmed with a more specific method before a positive determination is made.

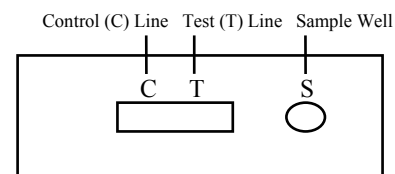
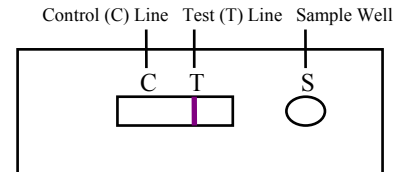


NEGATIVE: If both C line and T line appear in the viewing area, the test indicates that the THC level is below 50 ng/ml.

Note: A very faint line in the test region should be considered negative.



INVALID: If no C line develops within 5 minutes, repeat the assay with a new test device.



QUALITY CONTROL

- Built-in Control Features

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This test contains built-in control feature, the C line. The appearance of the burgundy C line indicates that the proper volume of specimen has been absorbed and capillary flow has occurred. If the C line does not appear within 5 minutes, the result is invalid. In this case, review the whole procedure and repeat test with a new device.

External Quality Control

Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay.

LIMITATIONS

- Results obtained by this device provide only a preliminary qualitative analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.
- This product is designed for testing human urine only.
- Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if added in the device. When suspected, collect a fresh specimen and repeat the test with a new device.
- Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES

This test is capable of detecting THC in urine at a cutoff level of 50 ng/ml, or higher.

PERFORMANCE CHARACTERISTICS

1. Sensitivity (Cutoff)

The Instant-View™ Marijuana (THC) Urine Cassette Test detects THC in urine at a cutoff level of 50 ng/ml.

2. Accuracy

A study was performed at a Reference Laboratory and Three Different Physician Office Laboratory (POL). Ninety-nine clinical samples analyzed by GC/MS from a toxicology laboratory were blind labeled and tested. Each sample was tested at each site, with Instant-View™ Marijuana (THC), and compared with GC/MS results. The test demonstrated an overall agreement of greater than 96.4%.

		Instant-View Test		
		-	+	Total
GC/MS	-	52	3*	55
	+	2**	42	44
Total		54	45	99

Note: * Samples are within 10% below the cutoff level of 50 ng/ml.

** Samples are within 18% above the cutoff level of 50 ng/ml.

*Resolution of Discrepant Results

Sample ID #	GC/MS Value	Instant-View Result
44	45 ng/ml	+
58	46 ng/ml	+
78	46 ng/ml	+
73	49 ng/ml	+
84	49 ng/ml	+
48	51 ng/ml	-
86	59 ng/ml	-

3. Precision

The precision was determined at three different POL locations, by persons with diverse educational backgrounds and work experience. Forty-pooled drug-free human urine specimens were spiked with THC at different levels. All specimens were blind labeled and tested. The results are as follow:

THC Conc. (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	-	+	-	+	-
0	8	0	8	0	8	0	8
37.5	8	0	8	0	8	0	8
50	8	7	1	6	2	8	0
62.5	8	8	0	7	1	8	0
100	8	8	0	8	0	8	0

The results indicate a 96.7 % concordance with the expected results.

4. Specificity

Cross-Reactivity

A study was conducted using THC-related compounds to determine the cross-reactivity of the Test.

THC structurally related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff level:	
Description	Concentration (ng/ml)
11-nor- Δ -8-THC-9-COOH	50
11-nor- Δ -9-THC-9-COOH	50
11-hydroxy- Δ -9-THC	100

Interference Substances

The following Analytes, a group of compounds, usually found in urine, and commonly prescribed therapeutic drugs were spiked in urine pools containing 0, or 50 ng/ml THC were tested, accordingly, in the Instant-View™ Marijuana (THC) Urine Test. No effects were observed from those Analytes at 1000 µg/ml.

Compounds tested and found not to cross-react with the test at the concentration of 1000 µg/ml in urine	
Acetaminophen	Codeine
Acetylsalicylic Acid	Cortisone
Amikacin	Dextromethorphan
Amitriptyline	Methadone
Ampicillin	Methanol
Arterenal	Oxalic Acid
Atropine	Penicillin-G (Benzylpenicillin)
Benzoic Acid	Pheniramine
Benzoylcegonine	Phenylpropanolamine
Caffeine	Ranitidine
(+)-Chlorpheniramine	Salicylic Acid
(+/-)-Chlorpheniramine	Thioridazine
Cocaine	Trifluoperazine

Biological Analytes	Concentration
Albumin(serum)	2,000 µg/ml
Bilirubin	1,000 µg/ml
Creatine	1,000 µg/ml
Hemoglobin	1,000 µg/ml
Glucose	2,000 µg/ml
PH	5.0 – 9.0
Vitamin C (L-Ascorbic Acid)	1,000 µg/ml
Uric Acid	1,000 µg/ml

There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results.

REFERENCES

- FDA Guidance for labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21/87.
- Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p186-188, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register, p. 53 (69): 11970 (1988).

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