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CE

THC Cassette

For Urine

REF

Catalog No.R24-450

IVD

FOR INVITRO DIAGNOSTIC USE ONLY

INTENDED USE

Immunospec 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 for health care professional use only.

This assay 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 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 obtained.

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.

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes 1) a burgundy-colored conjugate pad containing mouse anti-THC antibodies coupled to colloidal gold; and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with THC-BTG, and the Control line is coated with goat anti-rabbit 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 conjugated anti-THC antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of THC in the urine specimen is below the cutoff (50 ng/ml), the Test line should appear as a visible burgundy line. If the level of THC in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and forms a burgundy color line, regardless of the presence of THC.

REAGENTS AND MATERIALS SUPPLIED

- 25 test devices, each sealed in a pouch with a dropper pipette.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (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 the kit to temperatures over 30℃ (86°F).

15°C 30°C

SPECIMEN COLLECTION

1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

PRECAUTION

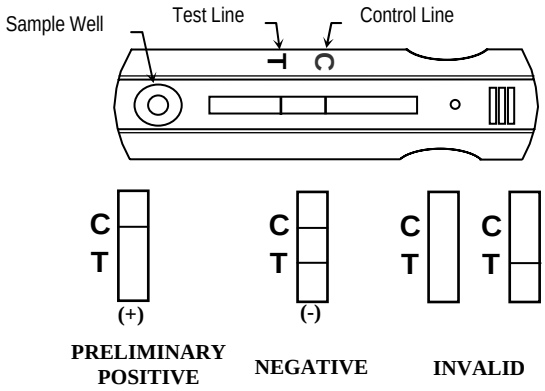
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing**.
2. Remove the test device from its pouch and place it on a flat surface. Label the device with specimen identification.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

***IMPORTANT*: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.**



Positive:

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

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

Negative:

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

Note: A very faint T line 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**
  Immunospec test contains a built-in control feature, the C line. The appearance of the burgundy C line indicates that an adequate 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**
  Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS

1. This test is for *professional in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative result. A more specific alternate chemical method must be used in order to obtain a confirmed result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if present in the sample. When suspected, collect a fresh specimen and repeat the test with a new device.
5. 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. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. Ninety nine (99) clinical samples were blind labeled and tested. Each sample was tested at each site, and compared with GC/MS results.

The results agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above 125% of the cutoff (positive). Fourteen (14) discrepancies were observed on the specimens at the level between 75% and 125% of the cutoff.

The overall agreement was 96.5%.

		THC Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	160	160	100%
	<75% (0-37.5)	0	36	36	100%
	75%-Cutoff (37.5-50)	11	13	24	54.2%
	Cutoff-125% (50-62.5)	17	3	20	85%
	Positive (>62.5)	156	0	156	100%
Total		184	212	396	96.5%

2. 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.

3. 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*

4. 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. No effects were observed from those analytes at 1000 µg/ml.

Compounds tested and found not to cross-react with the test at a 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*
Benzoylecgonine	*Phenylpropanalamine*
Caffeine	*Ranitidine*
(+)-Chlorpheniramine	*Salicyclic 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, 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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PIR24-450
Revision S
Revision date: 02/06/09