

274 mm x 218mm



Insight | THC

Rapid Competitive Immunochromatographic Assay for the detection of Tetrahydrocannabinol in human urine

DEVICE

DEVICE

INTENDED USE

INSIGHT-THC is a rapid, qualitative, immunochromatographic assay for the detection of tetrahydrocannabinol (THC) in human urine. This test is used to screen the tetrahydrocannabinol intoxication. For healthcare professional use only.

SUMMARY

Tetrahydrocannabinol (THC) is a central nervous system (CNS) depressant. THC is the most active of the principal constituents, as well as the major metabolite, of cannabinoids such as cannabis and hashish. Marijuana (cannabis) is sometimes used to treat individuals suffering from anorexia. Cannabinoids are usually smoked or administered orally, laced with some other drugs of abuse like cocaine. Higher doses used by abusers produce CNS effects, such as altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia and an increased heart rate. THC and its glucuronide are the primary urinary metabolites of cannabinoids. This means that the presence of THC in urine indicates the use of marijuana, cannabis and/or hashish. The half-life of THC is about 20 hours to 10 days, depending on the amount and potency of the drug used.

INSIGHT-THC detects the presence of tetrahydrocannabinol (THC) in urine specimen, qualitatively, at concentrations as low as 50 ng/ml.

PRINCIPLE

INSIGHT-THC is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - Agglutinating sera for Tetrahydrocannabinol conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Agglutinating sera for Tetrahydrocannabinol - colloidal gold conjugate complexes with the Tetrahydrocannabinol present in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is not immobilized by Tetrahydrocannabinol conjugated to BSA coated on the membrane, therefore forming no band. The absence of this band in the test region (T) indicates a positive result. In absence of Tetrahydrocannabinol in the test specimen, the Agglutinating sera for Tetrahydrocannabinol - colloidal gold conjugate and along with rabbit globulin-colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by the Tetrahydrocannabinol conjugated to BSA coated on the membrane, forming a pink coloured band indicating a negative result.

The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink coloured band. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

- A. Each INSIGHT-THC kit contains individual pouches each containing a
1. **DEVICE** : Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for Tetrahydrocannabinol and rabbit globulin, Tetrahydrocannabinol conjugated to BSA and Agglutinating sera for rabbit globulin at the respective regions.
 2. **PIPETTE** : Sample applicator.
 3. Desiccant pouch.
- B. Package insert.

REF	10807010	10807050

OPTIONAL MATERIAL REQUIRED

Variable volume precision micropipettes, stopwatch.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4 - 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

Insight

NOTE

1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimen as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

1. INSIGHT-THC uses human urine as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. A clean dry plastic or glass container may be used for specimen collection.
4. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
5. Refrigerated specimens must be brought to room temperature prior to testing.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of INSIGHT-THC device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. *Once opened, the device must be used immediately.*
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Holding the sample applicator vertically, carefully dispense exactly two drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 50 µl of test specimen into the specimen port (S).
8. Start the stopwatch. Read the results at the end of 5 minutes. Do not interpret the results beyond 8 minutes.

INTERPRETATION OF RESULTS

Negative Result:



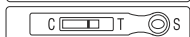
Two pink coloured bands appear at the control region (C) and test region (T). This indicates absence of tetrahydrocannabinol in the specimen.

Positive Result:



One pink coloured band appears at the control region (C). This indicates that the specimen contains detectable amount of tetrahydrocannabinol.

Invalid Result:



The test result is invalid if no band appears either at the control region (C) or test region (T). In such cases, verify the test procedure and repeat the test with a INSIGHT-THC device.

Important: A negative test result indicates that the analyte (drug) is either absent or is present below the detection threshold of the test kit.

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT-THC is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 5 minutes. However, some samples may take a longer time to flow. Therefore, negatives should be confirmed only at 8 minutes. Do not interpret the results beyond 8 minutes.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. The assay is designed for use with human urine only.
5. A preliminary positive result indicates only the presence of tetrahydrocannabinol and does not indicate or measure intoxication.

6. There is a possibility that technical/or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results. See specificity section that will produce positive results, or that do not interfere with the test performance.
7. If adulteration is suspected, the test should be repeated with a new sample.
8. Certain over the counter or prescription medications (or certain foods) may cause false results.
9. The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half life, the user's age, weight, activity and diet.
10. **This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.**

PERFORMANCE CHARACTERISTICS

1. **Sensitivity** : INSIGHT-THC detects THC at concentrations equal to or greater than 50 ng/ml.
2. **Specificity** : Interference of substances that may be present in urine specimen, as well as effect of sample pH and specific gravity was also studied.
 - a. Cross-reactivity of non-THC related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using assay devices.
 - b. No cross-reactivity was detected with the substances listed in table I. Table II lists THC related substances and concentrations that produced results approximately equivalent to the cut-off level for THC.

Table I:

The following compounds were found not to cross react at concentrations up to 100µg/ml.

Acetaminophen	Guaiacol Glyceryl Ether
Acetone	Hemoglobin
Albumin	Imipramine
Amitriptyline	(+/-) - Isoproterenol
Ampicillin	Lidocaine
Aspartame	(1R,2S) - (-) - N- Methyl - Ephedrine
Aspirin	(+) - Naproxen
Atropine	(+/-) - Norephedrine
Benzocaine	Oxalic Acid
Bilirubin	Penicillin - G
Caffeine	Pheniramine
Chloroquine	Phenothiazine
(+) - Chlorpheniramine	1 - Phenylephrine
(+/-) - Chlorpheniramine	Phenylethylamine
Creatine	Procaine
Dexbrompheniramine	Quinidine
Dextromethrophan	Ranitidine
4-Dimethylaminoantipyrine	Riboflavin
Dopamine	Sodium Chloride
(+/-) Ephedrine	Sulindac
(-) - Ephedrine	Tyramine
(+) - Epinephrine	Vitamin C
Erythromycin	Furosemide
Ethanol	Glucose

Table II:

The following structurally related compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

Compound	Concentration (ng/ml)
11-nor- Δ 8-THC-9-cacoxyllic acid	50
11-nor- Δ 9-THC-9-cacoxyllic acid	50
11-hydroxy- Δ 9-tetrahydrocannabinol	1000
Δ 8-tetrahydrocannabinol	7500
Δ 9-tetrahydrocannabinol	10000
Cannabinol	10000
















WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1). www. drug detection. net/drug. html (2). Klabunde R.E., Cardiovascular Pharmacology Concepts; Beta Adrenoceptor Antagonists (Beta Blockers), Sympathomimetics, 2006. (3). Wu. AH, Onigbhinde TA, Wong SS, Johnson KG, Evaluation of full scanning GC/ion trap MS of NIDA drugs of abuse urine testing in urine. J. Anal. Toxicol. 1992, May, Jun; 16(3) pgs 202-206. (4). Drugs and Human Performance, FACT SHEETS Cannabis, Amphetamines. (5). Kreek M.J. and Hartmann N. Chronic use of opiods and anti psychotic drugs, side effects , effects of endogenous opiods and toxicity; Annals New York academy of Science pgs 151-172. (6). Drugs of Abuse, Drug Enforcement Administration (DEA) Barbiturates pg 52, Benzodiazepines pg 53, Cocaine pg 45. (7) Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	 IVD In vitro Diagnostic Medical Device	 This side up	 PS Production site
 Use by	 REF Catalogue Number	 DEVICE Device	 EC REP Authorized Representative in the European Community
 Contains sufficient for <n> tests	 LOT Batch Number / Lot Number	 PIPETTE Disposable Plastic Sample Applicator	



PS

GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH,
ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202,
INDIA. Website: www.tulipgroup.com

PLOT NOS. 92/96, PHASE II C, VERNA IND. EST.,
VERNA, GOA-403 722, INDIA.

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

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