drugtestsource
www.drugtestsource.com

Drug Scan 5 Test

INTENDED USE

The INSTACHECK Drug Scan 5 for THC / Cocaine / PCP / Morphine 2000 / Methamphetamine is an in vitro screen test for the rapid detection of 11-nor-Δ_9-Tetrahydrocannabinol-9-carboxylic acid (THC), cocaine and
its metabolite, benzoylecgonine, PCP, morphine, and methamphetamine in human urine above the following concentrations.

THC	**11-nor-Δ_9-THC-9-COOH**	**50 ng/ml**
COC	**Benzoylecgonine**	**300 ng/ml**
PCP	**Phencyclidine**	**25 ng/ml**
MOR	**Morphine**	**2000 ng/ml**
MET	**Methamphetamine**	**1000 ng/ml**

The test is used to obtain visual qualitative result and is intended for professional use. It is not intended for over the counter sale to nonprofessionals.
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.

SUMMARY AND EXPLANATION

Urine based screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for screening urine for drugs of abuse.
The INSTACHECK Drug Scan 5 Test is based on the principle of the highly specific immunochemical reactions of antigens and antibodies, which are used for the analysis of specific compounds in human urine. The Multi-Drug Screen is a rapid, visual, competitive panel immunoassay that can be used for the simultaneous, qualitative detection of 11-nor-Δ_9-tetrahydrocannabinol-9-carboxylic acid, benzoylecgonine, morphine, methamphetamine and phencyclidine in urine.

TEST PRINCIPLE

The INSTACHECK Drug Scan 5 Test is a one-step immunoassay in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs, which may be present in urine. The testdevice contains membrane strips that are pre-coated with drug-protein conjugates on the test bands. The drug antibody-colloidal gold conjugate pads are placed at one end of the membrane. In the absence of drugs in the urine, the solution of the colored antibody-colloidal gold conjugates move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zones on the test band region. The colored antibody-gold conjugates then attach to the drug-protein conjugates to form visible lines as the antibodies complex with the drug conjugates. Therefore, the formation of the visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (drug-protein conjugate)- colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result. A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test cartridge should be discarded. The presence of this colored band in the control region also serves 1) as verification that sufficient volume is added, 2) that proper flow is obtained, and 3) as reagent control.

REAGENTS AND MATERIALS PROVIDED

Each INSTACHECK Drug Scan 5 Test Kit contains:
1. Directions For Use
2. Test Device: 25 each. Each device contains two membrane strips. Both strips contain anti-rabbit antibody in the control band. One strip contains THC, benzoylecgonine and PCP bovine protein conjugates in the test bands and the corresponding drug antibody gold conjugates and rabbit antibody gold complex in the pad. The other strip contains drug bovine protein conjugate and morphine monoclonal antibody in the test bands. The pad is coated with methamphetamine monoclonal antibody, morphine bovine protein and rabbit antibody gold complexes.
3. Specimen Pipette: 25 each

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Clock or timer

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
4. Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

TEST STORAGE

The test kit should be stored at room temperature or refrigerated at 2 - 30°C (36 - 86°F) in the sealed pouch for the duration of the stated expiration date.

SAMPLE COLLECTION AND STORAGE

The INSTACHECK Drug Scan 5 Test is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. Urine samples should be collected in an appropriate container and collected so that testing may be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may be refrigerated at 2-8°C for 2 days or frozen at -20°C for a longer period of time. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

ASSAY PROCEDURE

IMPORTANT: Test device, patient's sample, and controls should be brought to room temperature (20-30°C) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the test device from the sealed pouch.
2. Draw the urine sample up the pipette and dispense 4 drops (approximately 0.2 ml) into each sample well. Avoid adding drops

Drug Scan 5 Test

drugtestsource www.drugtestsource.com

that contain air since air bubbles in the well may cause uneven flow or prevent the flow of the sample onto the test strip.
3. **Read result within 3 to 8 minutes after the addition of samples. Do not read result after 8 minutes.** If the drug test is left standing for longer than 8 minutes, the intensity of the colored lines may change or a new line may appear.

INTERPRETATION OF RESULTS

Negative: A color line adjacent to each drug name and in the control (C) region should be observed in the viewing window. The color intensity of the line for the drug may be weaker or stronger than that of the control line.
Positive: Color lines appear on the control region (C). The absence of a line in any drug region indicates a positive result for that drug.
Invalid: No line appears in the control region. Under no circumstances should a positive sample be identified until the control line (C) forms in the viewing area. If the control line (C) does not form, the test result is inconclusive and the assay should be repeated with a new device.
Note: *A very faint line on the test region indicates that the drug in the sample is near the cut-off level for the test. These samples should be considered negatives. They are to be confirmed with a more specific method before a positive determination is made.*

QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

LIMITATIONS OF THE TEST

1. The assay is designed for use with human urine only.
2. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
3. There is a possibility that technical or procedural error as well as other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.

PERFORMANCE CHARACTERISTICS

Precision
Data for two (25 control samples for each run) precision runs are as follows:
A. Controls with drugs at 50% below cut-off levels:

		Run 1		Run 2	
Drug	Conc. ng/ml	+ve	-ve	+ve	-ve
THC	25	0	25	0	25
COC	150	0	25	0	25
MORPHINE	1000	0	25	0	25
PCP	12.5	0	25	0	25
MET	500	0	25	0	25

B. Controls with drugs at 50% above cut-off levels:

		Run 1		Run 2	
Drug	Conc. ng/ml	+ve	-ve	+ve	-ve
THC	75	25	0	25	0
COC	450	25	0	25	0
MORPHINE	3000	25	0	25	0
PCP	37.5	25	0	25	0
MET	1500	25	0	25	0

Specificity
Structurally similar compounds for THC, cocaine, morphine, PCP and methamphetamine were tested for cross-reactivity in INSTACHECK Drug Scan 5 Test. Each compound tested was prepared in drug-free normal human urine. The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/ml) listed below:

THC related compounds	Concentration (ng/ml)
11-nor-Δ-8-tetrahydrocannabinol-9-carboxylic acid	50
11-hydroxy-Δ-9-tetrahydrocannabinol	2,500
Δ-9-tetrahydrocannabinol	10,000
Δ-8-tetrahydrocannabinol	7,500
Cannabinol	10,000
Cannabidiol	100,000

Cocaine related compounds	Concentration (ng/ml)
Benzoylecgonine	300
Cocaine	300
Ecgonine	>100,000
Ecgonine Methyl Ester	>100,000

Morphine related compounds	Concentration (ng/ml)
Codeine	2,000
Ethyl morphine	2,000
Hydromorphone	2,500

Methamphetamine related compounds	Concentration (ng/ml)
d-Methamphetamine	1,000
d-Amphetamine	50,000
Chloroquine	50,000
(+/-)-Ephedrine	50,000
l-Methamphetamine (1-Deoxyephedrine)	25,000
3,4 methylenedioxymethamphetamine	2,000
Procaine	10,000
β-Phenylethylamine	50,000
Ranitidine	50,000

PCP related compounds	Concentration (ng/ml)
Thienylcyclohexylpiperidine (TCP)	3,000
Venlafaxine Hydrochloride (Effexor®)	15,600

The following compounds were found not to cross-react when tested at concentrations up to 100 µg/ml:

Acetaminophen	Ethanol
Acetone	Furosemide
Albumin	Guaiacol Glyceryl Ether
Amitriptyline	Hemoglobin
Ampicillin	Imipramine
l-Amphetamine[1]	Isoproterenol
Aspartame	Lidocaine
Aspirin	Methylenedioxyamphetamine[1]
Atropine	N-Methyl-Ephedrine
Benzocaine	(+)-Naproxen
Bilirubin	Penicillin-G
Caffeine	Pheniramine
Chlorpheniramine	Phenothiazine
Creatine	L-Phenylephrine
Dextromethorphan	Procaine
4-Dimethylaminoantipyrine	Quinidine
Dopamine	Ranitidine
(+/-)-Ephedrine	Sulindac
(-)-Ephedrine	Tyramine
Erythromycin	Vitamin C

[1]These compounds apply only to methamphetamine.
Note: A full list of compounds will be provided upon request

REFERENCES

1. Baselt, R.C. *Disposition of Toxic Drugs and Chemicals in Man*, Biomedical Publications, Davis, CA, 1982.
2. *Urine testing for Drugs of Abuse*. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
3. Fed. Register, Department of Health and Human Services, *Mandatory Guidelines for Federal Workplace Drug Testing Programs*, 53, 69, 11970-11979, 1988.
4. McBay, A.J. *Clin. Chem*. 33, 33B-40B, 1987.
5. Gilman, A.G., and Goodman, L.S. *The Pharmacological Basis of Therapeutics*, eds. MacMillan Publishing, New York, NY, 1980.