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"See Now" Cocaine Strip/Cassette Test Urine



For in vitro Diagnosis Use
Product Code: SN 7.4

INTRODUCTION

The "See Now" Cocaine (COC) Test is a rapid and convenient immunochromatographic in vitro assay. It is intended for the qualitative detection of the presence of COC and its metabolites in urine at or above the cutoff level of 300 ng/ml. The device is designed for professional use. This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed.

SUMMARY OF THE TEST

Cocaine is a local anesthetic and central nervous system stimulant. Prepared from Coca leaves, the pharmacological properties of cocaine, such as stimulating and euphoric effects, have been known for centuries. Cocaine had been used medicinally as a local anesthetic agent, but its addictive properties have minimized its modern daily use. Cocaine is considered one of the most highly reinforcing drugs abused today. It is most often self-administered by intravenous injection, nasal insufflations, and inhalation³. Its smoked form (freebase or crack) appears to be extremely addicting because of the rapid onset. Elimination of cocaine is predominantly controlled by its biotransformation. From 75% to 90% of a dose is converted to the inactive metabolites ecgonine methyl ester and benzoylecgonine, which are excreted in the urine for several days after use of the parent drug. Immunoassays for detection of cocaine abuse are designed to detect the longer lived metabolite-benzoylecgonine in urine at concentrations of 300 ng/ml or greater. A positive urine assay for cocaine metabolites suggests cocaine use during the past few days, and does not mean the parent drug is present in the patient's blood.

The "See Now" Cocaine Test device contains mouse monoclonal anti-Cocaine antibody colloidal gold conjugate predried on a pad. Cocaine-BSA conjugates antigen (on test region) and goat anti mouse IgG (on control region) are coated and immobilized on a reaction membrane.

The principal of the "See Now" Cocaine Test is a solid phase, competitive inhibition immuno-chromatographic assay, in which a chemically labeled drug (drug conjugate) competes with the drug that may be present in urine, for limited antibody binding sites. When the absorbent pad is soaked with urine, the urine will migrate via capillary action toward the test window where the test reaction occurs. A negative specimen produces two distinct color bands, one in the test zone and one in the control zone; A positive specimen produces only one color band in the control zone. To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

SPECIMEN COLLECTION AND STORAGE

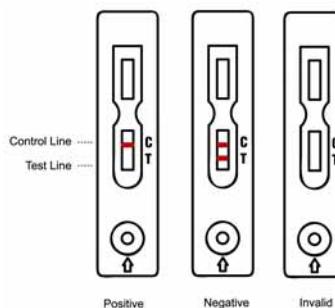
- Urine specimen may be collected at any time in a clean, dry container without preservatives.
- If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing or frozen at -20°C for longer period of time.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.

- Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification.
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface.
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well.
- For strip test, immerse the strip into the urine cup and take out the strip after 10 sec. Lay the strip on a flat, clean, dry, non-absorbent surface.
- Read the results at 10 minutes. Ensure that the background of the test area is white before interpreting the result.

INTERPRETATION OF RESULTS



Positive

Only one color band appears at the control region. No apparent band at the test region. This indicates that drug presence is above the cutoff concentration.

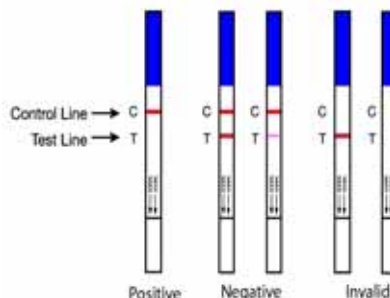
Negative

Two distinct color bands appear at the control and test regions. This indicates that there is no drug in the sample or drug presence is below the cutoff concentration.

Invalid

No visible band at the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.

Note: A faint line at the test region indicates the drug in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.



STORAGE AND STABILITY

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

- FOR IN VITRO DIAGNOSTIC USE ONLY.**
- Don't use it after the expiration date.
- The test device should not be reused.

PERFORMANCE CHARACTERISTICS

Sensitivity

The "See Now" Cocaine Urinary Test Strips detects Cocaine and its metabolites in urine at concentrations equal to or greater than 300 ng/ml.

Specificity

A study was conducted with the "See Now" Cocaine Urinary Test to determine the cross-reactivity of Cocaine-related compounds with the test

device (Table I).

Table-I Concentration of Cocaine-related compounds showing a positive response approximately equivalent to the Cocaine cut off set for the test.

Structurally related compounds	ng/ml
Benzoylecgonine	300
Cocaine HCl	600
Cocaethylene	5000
Ecgonine	10000

A separate study was conducted to determine the cross-reactivity of non-Cocaine related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in Table II.

Table- II Compounds tested and found not to cross-react with the test at a 1000 µg/ml concentration in urine

Amobarbital	Morphine	Desipramine
Butabarbital	Codeine	Doxepin
Hexobarbital	6-monoacetylmorphine	Imipramine
Pentobarbital	Ethylmorphine	Maprotiline
Phenobarbital	Heroin	Nortriptyline
secobarbital	Morphine-3-β-D-Glucuronide	Promazine
Alorazepam	Nalorphine	Promethazine
Bromazepam	Hydrocodone	Protriptyline
Clonazepam	Hvdromorphone	Trimipramine
Diazepam	Oxycodone	Acetaminophen
Estazolam	Levorphanol	Acetylsalicylic Acid
Flunitrazepam	Naloxone	Amikacin
Flurazepam	Thebaine	Ascorbic acid
Lorazepam	Norcodeine	Aspartame
Nitrazepam	Phencyclidine	Atropine Sulfate
Nordiazepam	Phencyclidine Morpholine	Benzoic Acid
Oxazepam	4hydroxyphencyclidine	Caffeine
Prazepam	Amirtotiline	Deoxyephedrine
Temazepam	Clomipramine	Dextromethorphan
Trazolam	Cyclobenzaprine	Gentamic acid
Δ ⁸ -Tetrahydrocannabinol	d-Amphetamine	Histamine
Δ ⁹ -Tetrahydrocannabinol	d,l-Amphetamine	Methaqualone
Cannabinol	Phentermine	Pendimethazine
Cannabidiol	l-amphetamine	Penicillin G
11-Nor-Δ ⁸ -Tetrahydrocannabinol carboxylic acid	3,4-Methylenedioxymethylamphetamine (MDMA)	Quinine
11-Nor-Δ ⁹ -Tetrahydrocannabinol carboxylic acid	d,l-3,4-Methylenedioxymethylamphetamine (MDMA)	Ranitidine
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	3,4-Methylenedioxymethylamphetamine (MDA)	Sodium Salicylate
Methadone	Pseudoephedrine	Tryptophan
Diphenhydramine	Ephedrine	Tetracycline
Dextromethorphan	l-methamphetamine	Tetrahydrozoline
Doxylamine	d-methamphetamine	

• Interference Testing

The following conditions were found not to interfere with the test.

Ethanol	1%
Methanol	1%
EDTA	80 mg/dl
Albumin	2,000 mg/dl
Glucose	2,000 mg/dl
Bilirubin	1,000 µg/dl
Hemoglobin	1,000 µg/dl
Urinary Test pH:	pH 3 – pH 9
Specific Gravity:	1.003 – 1.040

• Accuracy

Accuracy of the “See Now” Cocaine Urinary Test Device has been evaluated. A total of 80 clinic samples tested (40 negative and 40 positive), The two assays gave an overall of 97.5% .

Conc. of Sample (ng/ml)	No. of test	Results (# Neg/ #Pos)			
		Lot 1	Lot 2	Lot 3	Total
< 150	35	35 / 0	35 / 0	35 / 0	105 / 0
150 - 299	5	4 / 1	4 / 1	4 / 1	12 / 3
300 - 450	5	1 / 4	1 / 4	1 / 4	3 / 12
> 450	35	0 / 35	0 / 35	0 / 35	0 / 105
% of Negative				97.5 %	
% of Positive				97.5 %	
% of overall				97.5%	

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• Reproducibility

The precision was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable inter lot variation when testing both positive and negative samples across three different lots of devices.