First Romanian rapid tests manufacturer !

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"See Now" Opiate Strip/Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.9

INTRODUCTION

The *"See Now"* Opiate (OPI) Test is intended for the qualitative detection of the presence of OPI and its metabolites in urine at or above the cutoff level of 2000 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

Morphine, codeine, and semisynthetic derivatives of morphine belong to the class of drugs called opiates Morphine being a major metabolite of both heroin and codeine[1], its presence in urine has been used as an indicator of opiate use [2, 3]. Both morphine and codeine are naturally occurring alkaloids from opium. Heroin, a semisynthetic derivative (diacetylmorphine) of morphine, is more potent than morphine and is strictly a drug of abuse[4]
An opiate acts primarily on the opiate receptors to exert its effects on the central nervous system[5]. Codeine, commonly used in analgesics and cough medicine, and morphine, used in analgesics, are prescription drugs. Under the "analgesic ladder" approved by the World Health Organization, Morphine is considered to be the third and last step, in which it replaces weaker painkillers if necessary. Medical usage of morphine includes the relief of moderately severe to severe pains, relief of difficult or labored breathing, or suppression of diarrhea.
Morphine is metabolized extensively, with only 2-12 percent excreted as unchanged morphine in the urine[4,6,7]. Large amounts (60-80 percent) of the conjugated metabolites (glucuronides) are excreted in the urine, with small amounts (5-14 percent) being excreted in the feces. The quantitatively most important metabolite is morphine-3-glucuronide, which is excreted in the urine to an extent of 67-70 percent of the given dose in 48 hours. The half-life for morphine has been reported in the range of 1.7-4.5 hours.
Opiate and its metabolites may be detected in urine as a result of heroin, morphine, codeine, or poppy seed intake. Immunoassay testing has been developed for the determination of Opiate in urine.
The *"See Now"* Opiate Test device contains mouse monoclonal anti-Morphine antibody colloidal gold conjugate predried on a pad. Morphine-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"* Opiate 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.

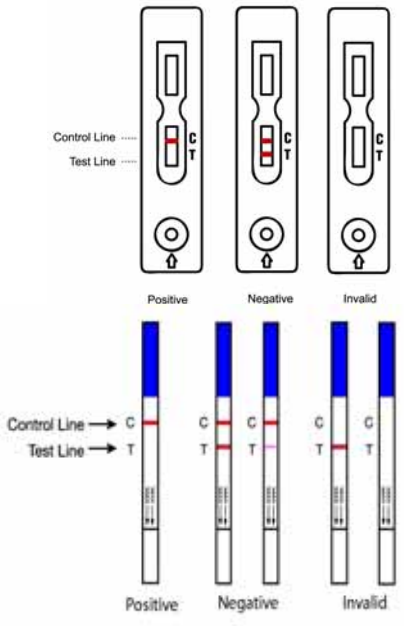
SPECIMEN COLLECTIONAND STORAGE

- 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 –20ºC 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"* Opiate Test Strips detects Morphine and its metabolites in urine at concentrations equal to or greater than 2000 ng/ml.

- Specificity

A study was conducted with The *"See Now"* Opiate Urinary Test Strips to determine the cross-reactivity of Morphine-related compounds with the test device (Table I).

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

Structurally related compounds	ng/ml	Structurally related compounds	ng/ml
Morphine	2000	Hydromorphone	5000
Morphine-3-β-D-Glucuronide	2000	Heroin	5000
Codeine	2000	Oxycodone	10000
6-monoacetylmorphine	5000	Levorphanol	20000
Ethylmorphine	5000	Naloxone	20000
Nalorphine	10000	Thebaine	50000
Hydrocodone	10000	Norcodeine	20000

A separate study was conducted to determine the cross-reactivity of non-Morphine 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

Amobartital	Cannabinol	Maprotiline
Butabarbital	Cannabidiol	Nortriptyline
Hexobarbital	Methadone	Promazine
Pentobarbital	Diphenhydromine	Promethazine
Phenobarbital	Dextromethorpham	Protriptyline
secobarbital	Doxylamine	Trimipramine
Alprazolam	Δ^8-Tetrahydrocannabinol	Acetaminophen
Bromazepam	Δ^9-Tetrahydrocannabinol	Acetylsalicylic Acid
Clonazepam	d,l-Amphetamine	Amikacin
Diazepam	Phentermine	Ascorbic acid
Estazolam	d-methamphetamine	Aspartame
Flunitrazepam	Ephedrine	Atropine Sulfate
Flurazepam	Pseudophedrine	Benzoic Acid
Lorazepam	l-methamphetamine	Caffeine
Nitrazepam	l-amphetamine	Deoxyephedrine
Nordiazepam	Phencyclidine	Dextromethorphan
Oxazepam	Phencyclidine Morpholine	Gentesic acid
Prazepam	4hydroxyphencyclidine	Histamine
Temazepam	Amitryptyline	Methaqualone
Trazolam	Clomipramine	Pendimetrazine
Benzoylecgonine	Cyclobenzaprine	Penicillin G
Cocaine HCl	Desipramine	Quinine
Cocaethylene	Doxepin	Ranitidine
Ecgonine	Imipramine	Sodium Salicylate
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	3,4-Methylenedioxyethylamphetamine (MDEA)	Tryptophan
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	d,l-3,4-Methylenedioxymethamphetamine (MDMA)	Tetracycline
11-Hydroxy-Δ^9-Tetrahydrocannabinol	3,4-Methylenedioxymethamphetamine (MDA)	Tetrahydrozoline

- 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"* Opiate 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 95%.

Conc. of Sample (ng/ml)	No. of test	Results (# Neg/ #Pos)			
		Lot 1	Lot 2	Lot 3	Total
< 1000	35	35 / 0	35 / 0	35 / 0	105/ 0
1000- 1999	5	3 / 2	3 / 2	3 / 2	9 / 6
2000 - 3000	5	2 / 3	2 / 3	2 / 3	6/ 9
> 3000	35	0 / 35	0 / 35	0 / 35	0 / 105
% of Negative					95 %
% of Positive					95%
% of overall					95%

- 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.