First Romanian rapid tests manufacturer !

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"See Now" Methadone Strip/Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.8

INTRODUCTION

The *"See Now"* Methadone (MTD) Test is intended for the qualitative detection of the presence of Methadone 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

Methadone, a synthetic opioid, is a commonly used substitute for heroin or other abused opiates in drug maintenance treatment clinics[1,2]. It is administered orally or intravenously and is metabolized in the liver. Excretion occurs through the kidneys in concentrations of 5 mg/ml or greater. Twenty-four hours after a dose is administered, urine levels of methadone maintenance patients typically range from 1 to 5 µg/ml[3-6]. Historically, a number of techniques have been employed for methadone detection in biological samples, including gas chromatography/mass spectrometry (GC/MS), ultraviolet spectroscopy, thin-layer chromatography, enzyme immunoassay and radioimmunoassay.
The *"See Now"* Methadone Test device contains mouse monoclonal anti-Methadone antibody colloidal gold conjugate predried on a pad. Methadone-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"* Methadone 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.

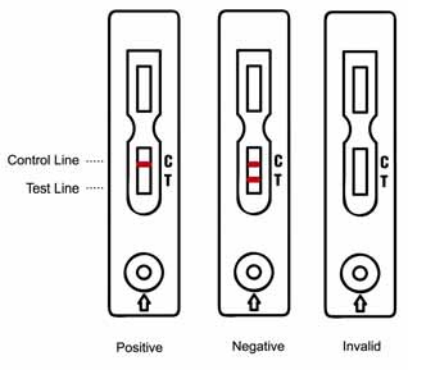
SPECIMEN COLLECTIONAND STORAGE

- 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.

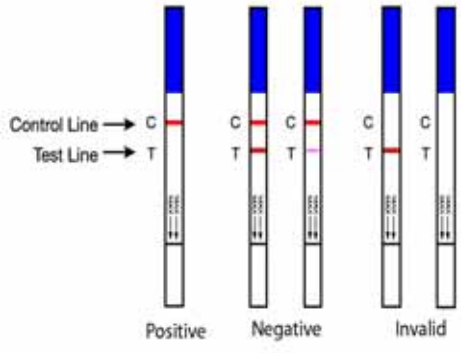
TEST PROCEDURE

- 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.
- Do not use after the expiration date shown on the pouch.
- Dispose of the used material as biological waste.
- Clean up spills thoroughly using an appropriate intermediate to high-level disinfectant.
- Keep out of children's reach.

PERFORMANCE CHARACTERISTICS

- Sensitivity

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

Specificity

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

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

Structurally related compounds	ng/ml
Methadone	300
Diphenhydromine	50000
Dextromethorpham	100000
Doxylamine	100000

A separate study was conducted to determine the cross-reactivity of non-Methadone 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	Morphine	Desipramine
Butabarbital	Hydromorphone	Doxepin
Hexobarbital	Codeine	Imipramine
Pentobarbital	6-monoacetylmorphine	Maprotiline
Phenobarbital	Ethylmorphine	Nortriptyline
secobarbital	Nalorphine	Promazine
Alprazolam	Hydrocodone	Promethazine
Bromazepam	Levorphanol	Protriptyline
Clonazepam	Heroin	Trimipramine
Diazepam	Oxycodone	Acetaminophen
Estazolam	Morphine-3-β-D-Glucuronide	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	d-Amphetamine	Deoxyephedrine
Temazepam	d,l-Amphetamine	Quinine
Trazolam	Phentermine	Gentesic acid
Benzoylecgonine	d-methamphetamine	Histamine
Cocaine HCl	Ephedrine	Methaqalone
Cocaethylene	l-methamphetamine	Pendimetrazine
Ecgonine	l-amphetamine	Penicillin G
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	3,4-Methylenedioxymethamphetamine (MDA)	Dextromethorphan
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	3,4-Methylenedioxyethylamphetamine (MDEA)	Ranitidine
11-Hydroxy-Δ^9-Tetrahydrocannabinol	d,l-3,4-Methylenedioxymethamphetamine (MDMA)	Sodium Salicylate
Δ^8-Tetrahydrocannabinol	Pseudophedrine	Tryptophan
Δ^9-Tetrahydrocannabinol	Amitryptyline	Tetracycline
Cannabinol	Clomipramine	Tetrahydrozoline
Cannabidiol	Cyclobenzaprine	

- 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"* Methadone 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 96.3%.

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	2 / 3	2 / 3	2 / 3	6/ 9
> 450	35	0 / 35	0 / 35	0 / 35	0 / 105
% of Negative					97.5 %
% of Positive					95.0 %
% of overall					96.3 %

- 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.