First Romanian rapid tests manufacturer !

rev1

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"See Now" Methamphetamine Strip/Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.6

INTRODUCTION

The *"See Now"* Methamphetamine (MET) Test is intended for the qualitative detection of the presence of MET and its metabolites in urine at or above the cutoff level of 1000 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

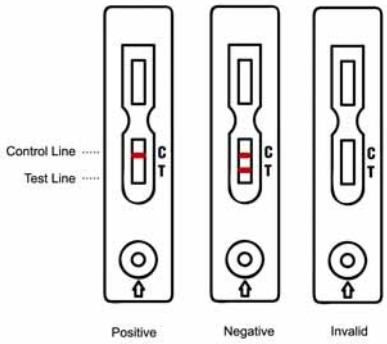
Methamphetamine is among the five most common illicit drugs. As a central nervous system stimulant, Methamphetamine produces potent dopaminergic and sympathomimetic effects, including euphoria, improved cognitive and sensory performance, generalized improvement in mood, increased physical endurance, and appetite suppression[2-4]. Large doses of methamphetamine could develop tolerances and physiological dependency and lead to its abuse [5-7]. Both d and L forms of the isomers are controlled substances, and the mandated allowable level for methamphetamine is set at 1000 ng/ml in urine. Methamphetamine is excreted primarily in urine, with little biliary excretion of the parent drug or metabolites [9]. The urinary pH plays an important role in the excretion of methamphetamine[10-13]. The percentage of the dose excreted as parent drug can range from as low as 2% in alkaline (pH 8.0) to 76% in acidic urine (pH 5.0). In normal urine (pH 6–8), 37–54% of a dose is excreted as parent drug and 4–7% as amphetamine
The *"See Now"* Methamphetamine Test device contains mouse monoclonal anti-Methamphetamine antibody colloidal gold conjugate predried on a pad. Methamphetamine-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"* Methamphetamine 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

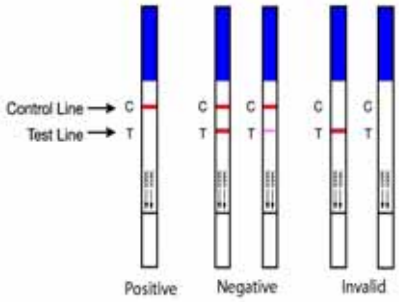
- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (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"* Methamphetamine Urinary Test detects Methamphetamine and its metabolites in urine at concentrations equal to or greater than 1000 ng/ml.

- Specificity

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

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

Structurally related compounds	ng/ml
d-methamphetamine	1000
(±) Methamphetamine	3000
d,l 3,4-Methylenedioxymethamphetamine (MDMA)	3000
3,4-Methylenedioxyethylamphetamine(MDEA)	5000
Ephedrine	20000
l-methamphetamine	50000
d-Amphetamine	100000
(±) 3,4-Methylenedioxyamphetamine (MDA)	100000
Pseudoephedrine	100000
l-amphetamine	100000

- 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"* Methamphetamine 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%

A separate study was conducted to determine the cross-reactivity of non-Methamphetamine 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	Morphine	Acetaminophen
Bromazepam	Morphine-3-β-D-Glucuronide	Acetylsalicylic Acid
Clonazepam	Codeine	Amikacin
Diazepam	6-monoacetylmorphine	Ascorbic acid
Estazolam	Ethylmorphine	Aspartame
Flunitrazepam	Nalorphine	Atropine Sulfate
Flurazepam	Hydrocodone	Benzoic Acid
Lorazepam	Hydromorphone	Caffeine
Nitrazepam	Heroin	Deoxyephedrine
Nordiazepam	Oxycodone	Dextromethorphan
Oxazepam	Levorphanol	Gentesic acid
Prazepam	Naloxone	Histamine
Temazepam	Thebaine	Methaqualone
Trazolam	Norcodeine	Pendimetrazine
Benzoylecgonine	Phencyclidine	Penicillin G
Cocaine HCl	Phencyclidine Morpholine	Quinine
Cocaethylene	4hydroxyphencyclidine	Ranitidine
Ecgonine	Amitryptyline	Sodium Salicylate
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	Clomipramine	Tryptophan
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	Cyclobenzaprine	Tetracycline
11-Hydroxy-Δ^9-Tetrahydrocannabinol	Desipramine	Tetrahydrozoline
Δ^8-Tetrahydrocannabinol	Doxepin	
Δ^9-Tetrahydrocannabinol	Imipramine	

- 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.