First Romanian rapid tests manufacturer !

rev1

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"See Now" Amphetamine Strip/Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.1

INTRODUCTION

The *"See Now"* Amphetamine (AMP) Test is a rapid and convenient immunochromatographic in vitro assay. It is intended for the qualitative detection of the presence of AMP 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

Amphetamine is central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Amphetamine can be taken orally, intravenously, by smoking or by nasal inhalation. Large doses of Amphetamine could develop tolerances and physiological dependency and lead to its abuse. Metabolism occurs in the liver either by deamination or hydroxylation of the aromatic ring. Amphetamine is also excreted in the urine unchanged. Both d and L forms of the isomers are controlled substances.
The *"See Now"* AMP Test device contains mouse monoclonal anti-amphetamine antibody colloidal gold conjugate pre-dried on a pad. AMP-BSA conjugates antigen (on test region) and goat anti mouse IgG (on control region) are coated and immobilized on a reaction membrane. The principle of the *"See Now"* AMP 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. 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.

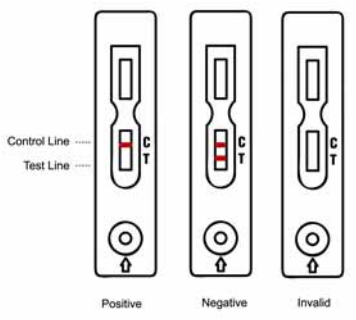
SPECIMEN COLLECTIONAND STORAGE

- 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

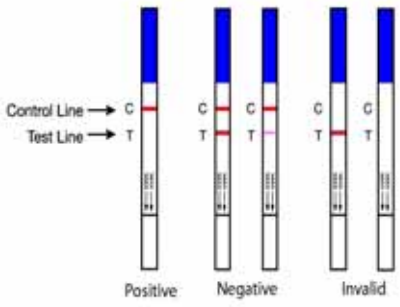
INTERPRETATION OF RESULTS



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"* Amphetamine Urinary Test detects amphetamine and its metabolites in urine at concentrations equal to or greater than 1000 ng/ml.

- Specificity

A study was conducted with the *"See Now"* Amphetamine Urinary Rapid Test to determine the cross-reactivity of amphetamine-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
d-Amphetamine	1000
3,4-Methylenedioxymethamphetamine (MDA)	2000
d,l-Amphetamine	3000
Phentermine	5000

d-methamphetamine	50000
Ephedrine	50000
Pseudophedrine	100000
3,4-Methylenedioxyethylamphetamine (MDEA)	100000
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	100000
l-methamphetamine	100000
l-amphetamine	100000

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

Acetaminophen	Ecgonine HCl	Pendimetrazine
Acetylsaclicylic Acid	Ecgonine Methyl Ester	Penicillin G
Amikacin	Glucose	Pentobarbital
Amitriptyline	Histamine	d-Propoxyphene
Ampicillin	Hydrocodone	Hydrochlorothiazide
Arterenol	Hydromorphone	Propanol
Aspartame	Indomathacin	Phencyclidine
Atropine Sulfate	Ketoprofen	Phenobarbital
Benzoic Acid	Levorphanol	Phentermine
Benzoylecgonine HCl	D -9-THC	Phenylpropanolamine
Caffeine	11-nor-D-9-carboxy-THC-9-COOH	L-Phenylephrine
Chlorpheniramine	Meperidine	Quinine
Chlorpropmazine HCl	Methylphenidate	Ranitidine
Cimetidine	Methadone	Sodium Salicylate
Codeine	Methaqalone	Tryptophan
Deoxyephedrine	Morp. Glucuronide	Tetracycline
Dextromethorphan	Morphine Sulfate	Tetrahydrozoline
Diazepam	Oxazepam	Theophylline
Diethylpropion	Oxycodone	Thioridazine
Diphenylhydantoin		Trifluoperazine
Doxylamine		Tryptophan

- 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
Specific Gravity:	1.003 – 1.040

- Accuracy

Accuracy of the *"See Now"* Amphetamine Urinary Test Device has been evaluated. A total of 80 clinic samples tested (40 negative and 40 positive), This study demonstrated that two assays have an overall of 96.3%.

Conc. of Sample (ng/ml)	No. of test	Results (# Neg/ #Pos)			
		Lot 1	Lot 2	Lot 3	Total
< 500		35 / 0	35 / 0	35/ 0	105 /0
500 - 999		1 / 4	1 / 4	1 / 4	3/ 12
1000-1500		2 /3	2 / 3	2 / 3	6 / 9
> 1500		0 /35	0 /35	0 / 35	0 /105
% of Negative				97.5%	
% of Positive				95 %	
% of overall				96.3 %	

- Reproducibility

The precision was determined by replicative 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.