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"See Now" Tricyclic Antidepresants Strip/Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.10

INTRODUCTION

The *"See Now"* Tricyclic Antidepressants (TCA) Test is intended for the qualitative detection of the presence of TCA 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

Tricyclic antidepressants (TCAs) are a type of prescription drug intended for clinically depressed patients. Unfortunately, they are becoming more frequently abused and are now one of the leading causes of death by drug overdose. TCAs are named after the drugs' molecular structure, which contains a similar three rings. The mechanism of how TCA works is not well understood. However, it is speculated that the drug inhibits the reuptake of neurotransmitters, norepinephrine and serotonin, etc. in nerve cells. In clinics, TCA is used to treat patients with depression, analgesia and nocturnal enuresis. Abuse of TCAs may lead to coma, respiratory depression, convulsions, blood pressure deviations, hyperprexia and severe cardiac conditions[5]. TCAs are excreted in urine mostly in the form of metabolites for up to ten days.
The *"See Now"* TCA Test device contains mouse monoclonal anti-TCA antibody colloidal gold conjugate predried on a pad. TCA-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"* TCA 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.

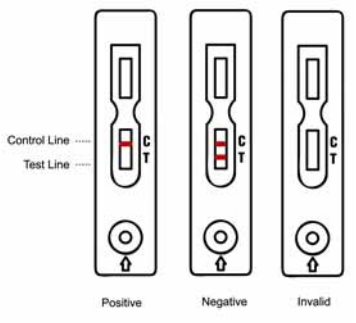
SPECIMEN COLLECTIONAND STORAGE

- 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.

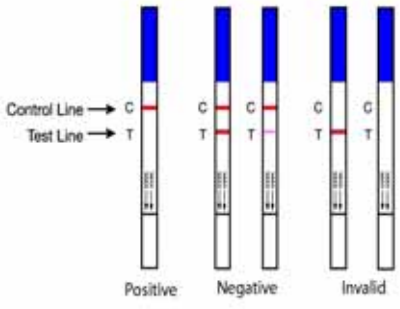
TEST PROCEDURE

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

- Specificity

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

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

Structurally related compounds	ng/ml	Structurally related compounds	ng/ml
Amitryptyline	1000	Nortriptyline	5000
Clomipramine	5000	Promethazine	100000
Desipramine	1000	Protriptyline	5000
Imipramine	1000	Trimipramine	5000
Maprotiline	100000		

A separate study was conducted to determine the cross-reactivity of non-TCA 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	d-Amphetamine
Butabarbital	Cannabidiol	d,l-Amphetamine
Hexobarbital	Methadone	Phentermine
Pentobarbital	Diphenhydromine	Pseudophedrine
Phenobarbital	Dextromethorpham	Ephedrine
secobarbital	Doxylamine	Amikacin
Alprazolam	Morphine	Acetaminophen
Bromazepam	Morphine-3-β-D-Glucuronide	Acetylsalicylic Acid
Clonazepam	Codeine	Ascorbic acid
Diazepam	6-monoacetylmorphine	Aspartame
Estazolam	Ethylmorphine	Atropine Sulfate
Flunitrazepam	Nalorphine	Benzoic Acid
Flurazepam	Hydrocodone	Caffeine
Lorazepam	Hydromorphone	Deoxyephedrine
Nitrazepam	Heroin	Dextromethorphan
Nordiazepam	Oxycodone	Gentesic acid
Oxazepam	Levorphanol	Histamine
Prazepam	Naloxone	Methaqalone
Temazepam	Thebaine	Pendimetrazine
Trazolam	Norcodeine	Penicillin G
Benzoylecgonine	Phencyclidine	Quinine
Cocaine HCl	Phencyclidine Morpholine	Ranitidine
Cocaethylene	4hydroxyphencyclidine	Tryptophan
Ecgonine	d-methamphetamine	
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	3,4-Methylenedioxymethamphetamine (MDA)	Sodium Salicylate
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	d,l-3,4-Methylenedioxymethamphetamine (MDMA)	Tetracycline
11-Hydroxy-Δ^9-Tetrahydrocannabinol	3,4-Methylenedioxyethylamphetamine (MDEA)	Tetrahydrozoline
Δ^8-Tetrahydrocannabinol	l-methamphetamine	
Δ^9-Tetrahydrocannabinol	l-amphetamine	

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"* TCA Urinary Test Device has been evaluated. A total of 81 clinic samples tested (41 negative and 40 positive), The two assays gave an overall of 92.6%.

Conc. of Sample (ng/ml)	No. of test	Results (# Neg/ #Pos)			
		Lot 1	Lot 2	Lot 3	Total
< 500	35	35 / 0	35 / 0	35 / 0	105/ 0
500 - 999	6	3/ 3	3 / 3	3 / 3	9 / 9
1000 -1500	8	2 / 6	2 / 6	2 / 6	6 / 18
> 1500	32	0 / 32	0 / 32	0 / 32	0 / 96
% of Negative					92.6 %
% of Positive					95 %
% of overall					93.8 %

- 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.