Cotinine Card

RAPU08A086

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History

Resume of change :

Previous Version : **190718-1**	**Current Version :** **230714**
Old DiaSource logo	New DiaSource logo on the front page

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Cotinine Card

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A rapid test for the qualitative detection of Cotinine (nicotine metabolite) in human urine.
For medical and other professional in vitro diagnostic use only.

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IN VITRO DIAGNOSTIC

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INTENDED USE

The Cotinine Card test is a rapid chromatographic immunoassay for the detection of Cotinine (nicotine metabolite) in human urine at the cut-off concentration of 200ng/ml. The following table lists compounds that are positively detected in urine by the Cotinine Card Test at 5 minutes

This assay provides only a qualitative, preliminary, analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.[1] While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.[3] Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.
The Cotinine Card Test is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in urine. The Cotinine Card Test yields a positive result when the Cotinine in urine exceeds 200 ng/mL.

PRINCIPLE

The Cotinine Card Test is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. Cotinine, if present in the urine specimen below 200 ng/mL, will not saturate the binding sites of antibody coated particles in the test . The antibody coated particles will then be captured by immobilized Cotinine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Cotinine level exceeds 200 ng/mL because it will saturate all the binding sites of anti-Cotinine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal anti-Cotinine antibody-coupled particles and Cotinine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For medical and other professional in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not use the test if the foil pouch is damaged
- Do not moisten nitrocellulose membrane with urine samples.
- Read the entire procedure carefully prior testing.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Humidity and temperature can adversely affect results.
- The used test device should be discarded according to federal state and local regulations.
- Do not reuse tests
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Tests should be kept out of direct sunlight.

- Do not freeze
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS PROVIDED

- CARD 20 x Test device in pouch
- PIPETTE 20 x Disposable sample droppers (in pouch)
- Package insert

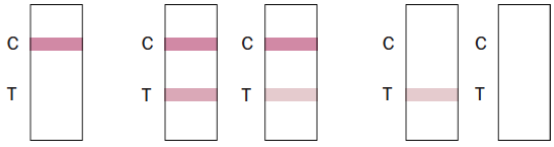
MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Positive and negative controls

DIRECTIONS FOR USE

1. **Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.**
2. Bring the pouch to room temperature before opening it.
3. Remove the Test from the sealed pouch and use it within one hour.
4. Place the test cassette on a clean and level surface.
5. Hold the dropper vertically and transfer 3 full drops of urine to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
6. Wait for the colored line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS



Positive: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the COT concentration is above the detectable cut-off level. (substances & cut-off concentrations see table on page 1).

Negative:* Two lines appear. One color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the COT concentration is below the detectable cut-off level.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test immediately and contact your local distributor.

* *Note:* The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Cotinine Card Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method[1,2.]
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- This test does not distinguish between drugs of abuse and certain medications.
- The Cotinine Card Test is intended for use with human urine specimens only.

EXPECTED VALUES

This negative result indicates that the Cotinine concentration is below the detectable level of 200ng/ml. Positive result means the concentration of Cotinine is above the level of 200ng/ml. The Cotinine Card Test has a sensitivity of 200ng/ml.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison was conducted using the Cotinine Card Test and GC/MS. The following results were tabulated:

COT		*GC/MS*		*Total Results*
Cotinine Card Test		*Positive*	*Negative*	
	Positive	*88*	*4*	*92*
	Negative	*3*	*155*	*158*
Total Results		*91*	*159*	*250*
% Agreement with this Test		96.7%	97.5%	97.2%

Analytical Sensitivity

A drug-free urine pool was spiked with Cotinine at the following concentrations: 0 ng/mL, 100 ng/mL, 150 ng/mL, 200 ng/mL, 250 ng/mL, 300 ng/mL and 600 ng/mL. The results demonstrate > 99% accuracy at +50% above and 50% below the cut-off concentration. The data are summarized below:

COT Concentration (ng/mL)	*Percent of Cut-off*	*n*	*Visual Result*	
			Negative	*Positive*
0	*0*	*30*	*30*	*0*
100	*-50%*	*30*	*30*	*0*
150	*-25%*	*30*	*27*	*3*
200	*Cut-off*	*30*	*15*	*15*
250	*+25%*	*30*	*4*	*26*
300	*+50%*	*30*	*0*	*30*
600	*3X*	*30*	*0*	*30*

Precision
A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Cotinine, 25% Cotinine above and below the cut-off, and 50% Cotinine above and below the 200 ng/mL cut-off was provided to each site. The results are given below:

COT Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity
Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 100 ng/mL and 300 ng/mL of Cotinine. The Cotinine Card Test was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH
The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Cotinine to 100 ng/mL and 300 ng/mL. The spiked, pH-adjusted urine was tested with the Cotinine Card Test in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

CROSS-REACTIVITY
A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cotinine positive urine. The following compounds show no cross-reactivity when tested with the Cotinine Card Test at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol
Acetone
Acetophenetidin
Acetylsalicylic acid
N-Acetylprocainamide
Albumin
Aminopyrine
Amitriptyline
Amobarbital
Amoxapine
Amoxicillin
l-Amphetamine
Ampicillin
Apomorphine
l-Ascorbic acid
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
(±)-Brompheniramine
Buspirone
Caffeine
Cannabidiol
Cannabinol
Chloral hydrate
Chloramphenicol
Chlordiazepoxide
Chloroquine
Chlorothiazide
(+)-Chlorpheniramine
(±)-Chlorpheniramine
Chlorpromazine
Chlorprothixene
Cholesterol
Cimetidine
Clomipramine
Clonidine
Cocaine
Codeine
Cortisone
Creatinine
Cyclobarbital
Cyclobenzaprine
Deoxycorticosterone
(-) Deoxyephedrine
R (-) Deprenyl
Dextromethorphan
Diazepam
Diclofenac
Dicyclomine
Diflunisal
Digoxin
4-Dimethylamino-antipyrine
Diphenhydramine
5,5-Diphenylhydantoin
Disopyramide
Doxylamine
Ecgonine
Ecgonine methylester
EDDP
Efavirenz (Sustiva)
EMDP
Ephedrine
l-Ephedrine
(±)-Epinephrine
l-Epinephrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethanol (Ethyl alcohol)
Ethyl-p-aminobenzoate
Etodolac
Famprofazone
Fenfluramine
Fenoprofen
Fentanyl
Fluoxetine
Furosemide
Gentisic acid
d (+) Glucose
Guaiacol glyceryl ether
Guaiacol glyceryl ether carbamate
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
Hydromorphone
p-Hydroxyamphetamine
o-Hydroxyhippuric acid
p-Hydroxymeth-amphetamine
p-Hydroxynorephedrine
Hydroxyzine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(-)-Isoproterenol
Isoxsuprine
Kanamycin
Ketamine
Ketoprofen
Labetalol
Levorphanol
Lidocaine
Lindane (hexachlorocyclohexane)
Lithium carbonate
Loperamide
Maprotiline
Meperidine
Mephentermine
Meprobamate
Methadone
d-Methamphetamine
l-Methamphetamine
Methaqualone
Methoxyphenamine
(-) 3,4-Methylenedioxy-amphetamine (MDA)
(+) 3,4 Methylendioxy-methamphetamine (MDMA)
Methylphenidate
Methyprylon
Methaqualone
Metoprolol
Morphine sulfate
Morphine-3-β-D-glucuronide
Nalidixic acid
Nalorphine
Naloxone
Naltrexone
Methyprylon
Metoprolol
Nimesulide
Norcodein
Morphine sulfate
α-Naphthaleneacetic acid
Norethindrone
Normorphine
d-Norpropoxyphene
Noscapine
d,l-Octopamine
Orphenadrine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Oxymorphone
Papaverine
Pemoline
Penicillin-G
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Pheniramine
Phenobarbital
Phenothiazine
Phentermine
trans-2-Phenyl cyclopropylamine
l-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine (d,l-norephedrine)
(±) Phenylpropanolamine
Prednisolone
Prednisone
5β-Pregnane-3α, 17α, 21-triol
Procaine
Promazine
Promethazine
d,l-Propanolol
d-Propoxyphene
d-Pseudoephedrine
Quinacrine
Quinidine
Quinine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital
Serotonin (5-hydroxytryptamine)
Sodium chloride
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3-acetate
Tetrahydrozoline
Thebaine
Theophylline
Thiamine
Thioridazine (chlorpromazine)
l-Thyroxine
Tolbutamide
cis-Tramadol
Trazodone
Triamterene
Trifluoperazine
Trimethobenzamide
Trimethoprim
Trimipramine
Tryptamine
d,l-Tryptophan
Tyramine
d,l-Tyrosine
Uric acid
Verapamil
Zomepirac

LIMITATIONS
It is impossible to check any and all - other than those drugs mentioned in the product insert - for cross-reactivity or any other influences to the to be detected drug of abuse (DOA).
If the patient takes a „cocktail“ of several different drugs or medication cannot be excluded that a non-reproducible cross-reaction can falsified the test result.

BIBLIOGRAPHY

1. Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

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