Atlas Medical

One Step Cotinine Test Cassette (Urine)

IVD For In-Vitro diagnostic and professional use only

Store at (2-30º C)

INTENDED USE

The Cotinine test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of Cotinine in human urine specimens. The presence of cotinine in human urine as low as 200 ng/ml can be detected in 5 minutes.

INTRODUCTION AND PRINCIPLE

Most experts and healthcare professionals agree that nicotine is unquestionably the most addictive drug in use today. The principle source of nicotine is tobacco products. Tobacco smoking or chewing results in the absorption of nicotine through the lung and buccal/nasal epithelium, after which nicotine is metabolized into 20 metabolites excreted in urine. Cotinine, a major metabolite of nicotine accumulates in the body with regular smoking. It is reported that Cotinine is stable in body fluids and has a relatively long half-life of approximately 17 hours. Therefore the detection of Cotinine is less dependent on the time of sampling than that of nicotine and other metabolites. Cotinine has been widely used as a bio-marker of tobacco exposure. Methods of analysis for Cotinine in biological fluids include gas chromatography, gas chromatography-mass spectrometry, HPLC, HPLC-mass spectrometry, EIA and RIA. These methods usually require special equipment and complicated operation procedures. For comprehensive information on drug testing including typical half-life or drug detection periods.

The Cotinine test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between Cotinine -dye conjugate and free Cotinine which may be present in the urine specimen being tested. When Cotinine is present in the urine specimen, it competes with Cotinine -dye conjugate for the limited amount of anti- Cotinine antibody which are immobilized on the nitrocellulose membrane. when the amount of Cotinine is equal or more than the cut-off, 200 ng/ml, it will prevent the binding of Cotinine -dye conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result. A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

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MATERIALS

Materials Provided

- Cotinine test device.
- Dropper.
- Instructions for use.

Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test Cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Cassette should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Cassette is stable through the expiration date printed on the label on the sealed pouch.
- The test Cassette must remain in the sealed pouch until use. 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 precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

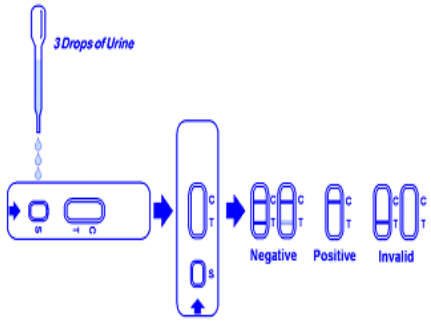
Specimen Storage

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

PROCEDURE

Allow the test Cassette, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test Cassette from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red 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

(Please refer to the illustration)

Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative result does not indicate the absence of drug in the specimen; it only indicates that the Cotinine level in the specimen is less than cut-off level.

Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication that the Cotinine level in the specimen is above the cut-off level.

Invalid:

If there are no colored bands in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A very faint colored band in test line zone indicates that the amount of Cotinine in the sample is near the cut-off level. These specimens and any positive samples should be confirmed by and alternate method such as GC/MS.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

2. Control standards can be used to validate reagent performance and establish test reliability. Controls which are not provided with this test are commercially available.

EXPECTED RESULTS

The Rapid Test is a qualitative assay. It identifies cotinine in human urine at a concentration of 200 ng/ml or higher. The concentration of the Cotinine cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

Sensitivity

The following table lists compounds that are detected by Rapid Tests.

Compounds	Cut-off (ng/ml)	Cross reactivity (%)
Cotinine	**200**	**100**

Interference testing

The following substances did not interfere with Rapid test.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

Specificity

The following compounds show no cross-reactivity at concentration up to 100 μg/ml unless specified.

4-Acetamidophenol	Erythromycin	Oxymetazoline
Acetophenetidin	⍰-Estradiol	Papaverine
N-Acetylprocainamide	Estrone-3-sulfate	Penicillin-G
Acetylsalicylic acid	Aspartame	Pentazocine
Aminopyrine	Fenoprofen	Pentobarbital
Amitryptyline	Furosemide	Perphenazine
Amobarbital	Gentisic acid	Phencyclidine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Phenobarbital
L-Ascorbic acid	Hydrochlorothiazide	Phentermine
D,L-Amphetamine	Hydrocortisone	L-Phenylephrine
Apomorphine	O-Hydroxyhippuric acid	⍰-Phenylethylamine

Ethyl-p-aminobenzoate		p-Hydroxy-Phenylpropanolamine
Atropine	methamphetamine	Prednisone
Benzilic acid	3-Hydroxytyramine	D,L-Propanolol
Benzoic acid	Ibuprofen	D-Propoxyphene
Benzoylecgonine	Imipramine	D-Pseudoephedrine
Benzphetamine	Iproniazid	Quinidine
Bilirubin	(⍰)-Isoproterenol	Quinine
(⍰)-Brompheniramine	Isoxsuprine	Ranitidine
Caffeine	Ketamine	Salicylic acid
Cannabidiol	Ketoprofen	Secobarbital
Chloralhydrate	Labetalol	Serotonin(5-Hydroxytyramine)
Chloramphenicol	Loperamide	
Chlordiazepoxide	Maprotiline	Sulfamethazine
Chlorothiazide	Meperidine	Sulindac
(⍰) Chlorpheniramine	Meprobamate	Temazepam
Chlorpromazine	Methadone	Tetracycline
Chlorquine	Methoxyphenamine	Tetrahydrocortisone, 3 Acetate
Cholesterol	(+)3,4-Methylenedioxy	
Clomipramine	amphetamine	Tetrahydrocortisone 3
(⍰-D glucuronide)		
Clonidine	(+)3,4-Methylenedioxymethamphetamine	
Cocaine hydrochloride	methamphetamine	Tetrahydrozoline
Cortisone	Nalidixic acid	Thiamine
(-) Cotinine	Nalorphine	Thioridazine
Creatinine	Naloxone	D, L-Tyrosine
Deoxycorticosterone	Naltrexone	Tolbutamide
Dextromethorphan	Naproxen	Triamterene
Diazepam	Niacinamide	Trifluoperazine
Diclofenac	Nifedipine	Trimethoprim
Diflunisal	Norethindrone	Trimipramine
Digoxin	D-Norpropoxyphene	Tryptamine
Diphenhydramine	Noscapine	D, L-Tryptophan
Doxylamine	D,L-Octopamine	Tyramine
Ecgonine ydrochloride	Oxalic acid	Uric acid
Ecgonine methylester	Oxazepam	Verapamil
(-)-ψ- Ephedrine	Oxolinic acid	Zomepirac

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REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry