# Cotinine Panel Dip Test

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%. While cotinine is thought to be an inactive metabolite, its 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. Nicotine and cotinine are rapidly eliminated by the kidney; Cotinine can be detected in urine up to 2-3 days after nicotine use.

## INTENDED USE

The Cotonine COT Panel Dip Tests is a rapid visual immunoassay for the qualitative, presumptive detection of Cotinine in human urine specimens at the cut-off concentrations listed below:

| Drug(Identifier) | Calibrator | Cut-off level | Minimum detection time | Maximum detection time |
|---|---|---|---|---|
| Cotinine(COT) | Cotinine | 200 ng/ml | 1-8 hours | 1-7 days |

For determination of smoking status only. Not intended for medical diagnostic use.

## PRINCIPLE

The Cotonine COT Panel Dip Tests detect Cotonine through a colored line representation on the test. During testing, the urine specimen reacts with the antibodies on the test pad reagents on the membrane.

If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

## WARINGS AND PRECAUTIONS

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is opened or damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

## STORAGE AND STABILITY

- The kit should be stored at 36°F-86°F(2°C-30°C) until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

## MATERIALS

**Materials Provided**

- Individually pouched test dipsticks
- Package insert

**Materials Required but Not provided**

- Timer

## SPECIMEN COLLECTION AND PREPARATION

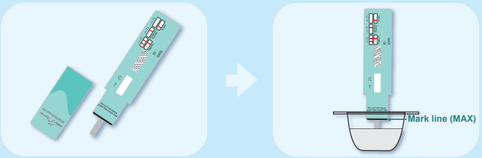
- The Cotonine COT Panel Dip Tests is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Cloudy or foamy specimens should be allowed to settle. Only clear samples should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

## TEST PROCEDURE

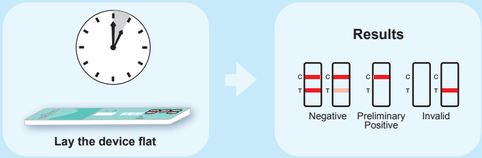
**Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.**

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and
3. expose the absorbent end.
4. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the "MAX" line printed on the front of the device.
5. Lay the device flat on a clean, dry, non-absorbent surface.
6. Read the result at 5 minutes. Do not read after 5 minutes.

Step 1:
Pull the cap off and immerse the strips into urine for 10 seconds,
Do not immerse past the mark line (MAX).

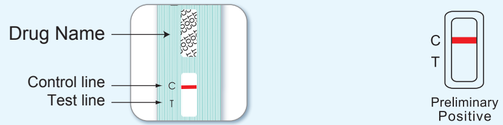



Step 2:
Read the result at 5 minutes. Do not read after 5 minutes.



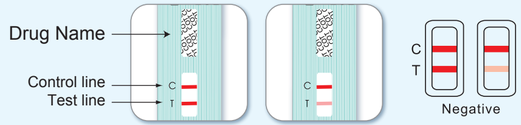

## INTERPRETATION OF RESULTS

**Positive (+)**
A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.



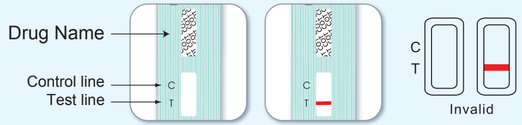
**Negative (-)**

A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.




**Invalid**

If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.




**Note:** There is no meaning attributed to line color intensity or width.

## QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted.

## PERFORMANCE CHARACTERISTICS

### A. Accuracy

The accuracy of the Cotonine COT Panel Dip Tests was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The resultswere >99.9% in agreement.

### B. Reproducibility

The reproducibility of the Cotonine COT Panel Dip Tests was verified by blind tests performed at four different locations. Samples with Cotinine concentrations at 50% of the cut-off were all determined to be negative, while samples with Cotinine concentrations at 200% of the cut-off were all determined to be positive

### C. Precision

Test precision was determined by blind tests with control solutions. Controls with Cotinine concentrations at 50% of the cut-off yielded negative results, and controls with Cotinine concentrations at 150% of the cut-off yielded positive results.

### D. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Cotonine COT Panel Dip Tests identified positive results at 5 minutes.

| Cotinine 200 related compounds. | Concentration (ng/ml) |
|---|---|
| (-)-Cotinine | 200 |
| Buprenorphine | 100,000 |

The following compounds yielded negative results up to a concentration of 100 µg/mL:

| | | |
|---|---|---|
| (-)-Ephedrine | Chlorpheniramine | Oxalic Acid |
| (+)-Naproxen | Creatine | Penicillin-G |
| (+/-)-Ephedrine | Dextromethorphan | Pheniramine |
| 4-Dimethyllaminoantiyrine | Dextrorphan tartrate | Phenothiazine |
| Acetaminophen | Dopamine | Procaine |
| Acetone | Erythromycin | Protonix |
| Albumin | Ethanol | Pseudoephedrine |
| Amitriptyline | Furosemide | Quinidine |
| Ampicillin | Glucose | Ranitidine |
| Aspartame | Guaiacol Glyceryl Ether | Sertraline |
| Aspirin | Hemoglobin | Tyramine |
| Benzocaine | Imipramine | Trimeprazine |
| Bilirubin | (+/-)-Isoproterenol | Venlafaxine |
| b-Phenylethyl-amine | Methadone | Ibuprofen |
| Caffeine | Vitamin C | Lidocaine |
| Chloroquine | | |

## LITERATURE REFERENCES


1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980


## MEANING OF SYMBOLS ON PACKAGE


Keep away from sunlight

Store between 36°F-86°F(2°C-30°C)


Keep dry


Do not re-use

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Any questions, please call us toll-free at

**1-855-822-6999**

Monday – Friday 9:00 a.m.-5:00 p.m. Central Time.

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Ver.201912