SBio COT Test

Rapid Competitive Test for detection of Nicotine (Cotinine) in human urine

REF	92100010
Σ	10 T

CE

Temperature Limitation	Manufacturer	PIPETTE — Disposable Plastic Sample Applicator	Do not reuse	Xn NaN_3; R22 S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Use by (Last day of stated month)	Consult Instructions for use	DEVICE — Device	BUF — Clearing Buffer	
Date of Manufacture	REF — Catalogue Number	Contains sufficient for <n> tests	EC REP — Authorised Representative in the European Community	
LOT — Batch Number/ Lot Number	IVD — *In vitro* Diagnostic Medical Device	This side up		

INTRODUCTION

SBio COT is a rapid competitive immunochromatographic assay to detect the presence of cotinine (a nicotine metabolite) in human urine specimen. This test is used to screen the Nicotine(Cotinine) intoxication. For healthcare professional use only.

SUMMARY

Cotinine is the first stage metabolite of nicotine, an alkaloid that produces stimulation of central nervous system (CNS). Nicotine is consumed either by smoking or chewing or snorting of tobacco. In addition to the tobacco, nicotine is also available as nicotine gum, transdermal patches and nasal spray. In 24 hours urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydrocotinine. Elimination profile of cotinine is more stable than unchanged nicotine. As a result, presence of cotinine in urine specimen is considered to be a good marker for determination of nicotine use.
SBio COT detects the presence of cotinine (a nicotine metabolite) in human urine specimen, qualitatively, at concentrations as low as 200 ng/ml.

PRINCIPLE

SBio-COT is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - Agglutinating sera for Cotinine conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Agglutinating sera for Cotinine - colloidal gold conjugate complexes with the Cotinine present in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is not immobilized by Cotinine conjugated to BSA coated on the membrane, therefore forming no band. The absence of this band in the test region (T) indicates a positive result. In absence of Cotinine in the test specimen, the Agglutinating sera for Cotinine -colloidal gold conjugate and along with rabbit globulin-colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by the Cotinine conjugated to BSA coated on the membrane, forming a pink coloured band indicating a negative result.
The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink coloured band. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

A. Each SBio COT kit contains individual pouches each containing a
   1. Device : Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for Cotinine and rabbit globulin, Cotinine conjugated to BSA and Agglutinating sera for rabbit globulin at the respective regions.
   2. Sample applicator.
   3. Desiccant pouch.

B. Package insert.

OPTIONAL MATERIAL REQUIRED

Precision micropipette capable of delivering 50 µl specimen, stopwatch.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4 - 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE

1. For *in vitro* diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use the device beyond expiry date.
3. Test devices are for single use only.
4. Read the instructions carefully before performing the test.
5. Handle all specimen as if potentially infectious.Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

1. SBio COT uses human urine as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. A clean dry plastic or glass container may be used for specimen collection.
4. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
5. Refrigerated specimens must be brought to room temperature prior to testing.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of SBio COT device to room temperature before testing.
2. Open a foil pouch by tearing along the “notch”.
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. ***Once opened, the device must be used immediately.***
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Holding the sample applicator vertically, carefully dispense exactly two drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 50 µl of test specimen into the specimen port (S).
8. Start the stopwatch. Read the results at the end of 5 minutes. Do not interpret the results beyond 8 minutes.

INTERPRETATION OF RESULTS

Negative Result:

Two distinct colored bands at result window indicate absence of cotinine or presence of less than 200 ng/ml cotinine concentration in specimen.

Positive Result:

Only one colored band at control area of the result window indicates presence of ≥ 200 ng/ml cotinine concentration in specimen.

Invalid Result:

The test result is invalid if no band appears at the control region(C) In such cases, verify the test procedure and repeat the test with a new device.

Important: A very faint line on the test region indicates that the cotinine in the 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 positive determination is made.

REMARKS

1. The deliberate slow reaction kinetics of Sbio COT is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 5 minutes. However, certain samples may take a longer time to flow. Therefore, negatives should be confirmed only at 8 minutes. Do not interpret the results beyond 8 minutes.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. The assay is designed for use with human urine only.
5. A positive result indicates only the presence of cotinine in specimen above the cutoff level mentioned; and does not indicate or measure intake of tobacco or any form of nicotine (either by smoking, chewing, snorting or by taking therapeutic substances).
6. There is a possibility that technical/or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results. See specificity section that will produce positive results, or that do not interfere with the test performance
7. If adulteration is suspected, the test should be repeated with a new sample.
8. Certain over the counter or prescription medications (or certain foods) may cause false results.
9. The length of time of nicotine use for which a positive result may occur is dependent upon several factors, including the frequency and amount of nicotine, metabolic rate, excretion rate, drug half life, the user's age, weight, activity and diet.
10. This test provides only a preliminary analytical test result. **Gas chromatography and mass spectrometry (GC/MS) is the preferred confirmatory method for this analyte detection.** Clinical consideration and professional judgment should be applied to the test results, particularly when preliminary positive results are indicated.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity** : SBio COT detects cotinine (a nicotine metabolite) at concentrations equal to or greater than 200 ng/ml.
2. **Specificity** : Interference of substances that may be present in urine specimen, as well as effect of sample pH and specific gravity was also studied.
   Cross-reactivity of non-cotinine related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using assay devices.
   No cross-reactivity was detected with the substances listed in table below.

Acetaminophen	(1R,2S) - (-) - N- Methyl - Ephedrine
Acetone	Hemoglobin
Albumin	Ibuprofen
Ampicillin	(+/-) - Isoproterenol
Ascorbic Acid	Ketamine
Aspartame	Levorphanol
Aspirin	Lidocaine
Atropine	(+) - Naproxen
Benzocaine	Niacinamide
Bilirubin	(+/-) - Norephedrine
Caffeine	Oxalic Acid
Chloroquine	Penicillin - G
(+) - Chlorpheniramine	Pheniramine
(+/-) - Chlorpheniramine	Phenothiazine
Creatine	1 - Phenyethylamine
Dexbrompheniramine	β - Phenylethylamine
Dextromethrophan	Procaine
Diphenhydramine	Quinidine
Dopamine	Ranitidine
(+/-) - Epinephrine	Riboflavin
Erythromycin	Sodium Chloride
Ethanol	Sulindac
Furosemide	Theophylline
Glucose	Tyramine
Guaiacol Glyceryl Ether	4 -Dimethylaminoantipyine

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1). www. drug detection. net/drug. html (2). Klabunde R.E., Cardiovascular Pharmacology Concepts; Beta Adrenoceptor Antagonists (Beta Blockers), Sympathomimetics, 2006. (3). Wu. AH, Onigbhinde TA, Wong SS, Johnson KG, Evaluation of full scanning GC/ion trap MS of NIDA drugs of abuse urine testing in urine. J. Anal. Toxicol. 1992, May, Jun; 16(3) pgs 202-206. (4). Drugs and Human Performance, FACT SHEETS Cannabis, Amphetamines. (5). Kreek M.J. and Hartmann N. Chronic use of opiods and anti psychotic drugs, side effects , effects of endogenous opiods and toxicity; Annals New York academy of Science pgs 151-172. (6). Drugs of Abuse, Drug Enforcement Administration (DEA) Barbiturates pg 52, Benzodiazepines pg 53, Cocaine pg 45. (7) Data on file: Tulip Diagnostics (P) Ltd.

Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

Plot Nos. 92/96, Phase II C, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Manufactured for:

Singapore SB Biosciences PTE Ltd.
11 Yishun Street 51, #04-23,The Criterion,
Singapore 767971

0722/VER-02

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain