COTININE (COT) RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

HOMEMED

INTENDED USE

The HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative, presumptive detection of Cotinine in human whole blood, serum or plasma specimens.
Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system 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. After nicotine is processed into cotinine, it passes into the bloodstream. Cotinine and other nicotine components are eliminated from blood through various processes of liver detoxification. It may be noted that these processes are slower than the processes of waste elimination carried out by the kidneys. In most cases, blood tests can detect cotinine for 1 to 3 days from the last known use of nicotine based products such as nicotine patches, nicotine gum, cigarettes, snuff, etc. The cotinine detection times in blood tests vary based on factors such as age, tobacco use, etc. Depending on the factors, blood tests can detect the chemical for 1 to 10 days before it becomes undetectable. The designed cut-off concentration and direct calibrator is as follows:

Parameter	Calibrator	Cut-off (ng/ml)
Cotinine (COT)	Cotinine	50

The HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) is used to obtain a visual qualitative test result. This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

PRINCIPLE

The HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. If cotinine is present in the blood specimen, it will compete against the respective drug conjugate for binding sites on the specific antibody.
During testing, a portion of the blood specimen migrates upward by capillary action. A drug, if present in the blood specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible coloured line will appear in the test line region of the drug strip. The presence of a drug above the cut-off concentration in the blood specimen will saturate all the binding sites of the antibody. Therefore, no coloured line will form in the test line region. A drug-positive blood specimen will not generate a coloured line in the test line region of the strip because of drug competition, while a drug-negative blood specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a coloured line will always appear at the control line region, indicating that the correct volume of specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS

Materials provided	Materials not provided
25 Cotinine (COT) Blood Test Cassettes	Timer
25 Disposable pipettes	
1 Package insert	

PRECAUTIONS

For *in vitro* diagnostic use only.

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Do not touch the reaction field, to avoid contamination.
- Read the entire procedure carefully prior to testing.
- Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Use test immediately after opening.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry 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.
- The product is humidity-sensitive and should be used immediately after opened.
- Any test in an improperly sealed pouch should be discarded.
- 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.

SPECIMEN COLLECTION AND STORAGE

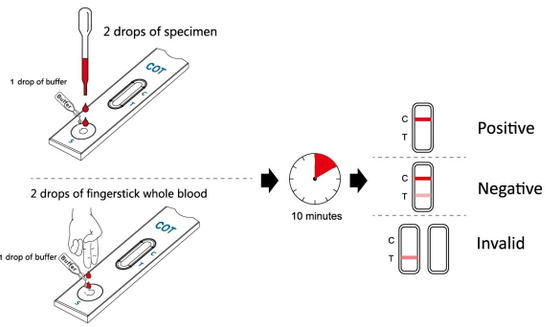
- The HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with whole blood (venous or from fingertip), serum or plasma.
- Collecting a blood sample from veins:
  1. Use a natriumheparine or lithiumheparine test tube to collect blood from veins. Do not use an EDTA test tube.
  2. The test should be carried out immediately after the sample has been collected.
- Collecting a blood sample from the fingertip:
  1. The patient's hand should be washed with soap and warm water or cleaned with an alcohol swab and allowed to dry.
  2. Massage the hand into the direction of the fingertip of the middle or the ring finger without touching the designated prick point.
  3. Use a lancet to prick the fingertip and wipe off the first drop of blood.
  4. Gently massage the finger in the direction of the fingertip to allow a drop of blood to form at the prick point.
  5. The test should be carried out immediately after the sample has been collected.

Note: Blood specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

IMPORTANT: Bring test, buffer, specimen and/or controls to room temperature (15-30°C) prior to testing. Do not open pouch until ready to perform the test.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean, flat surface. Label the test with patient or control identification.
3. Using the provided disposable pipette, transfer 2 drops of specimen (± 80 µl) of whole blood to the specimen well (S) of the cassette, then add 1 drop of buffer and start the timer. See illustration below. NOTE: Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the result area.
4. When using serum or plasma, do not add any buffer to the test.
5. The test result should be read at 10 minutes. Do not interpret the test result after 15 minutes.



INTERPRETATION OF RESULTS

(Refer to the illustration above)
Positive: Only one coloured line appears, in the control line region (C). No coloured line appears in the test line region (T). A positive test result indicates that the drug concentration exceeds the detectable level.
Negative: Two coloured lines appear. One line appears in the control line region (C) and another line appears in the test line region (T). A negative test result indicates that the drug is absent or the drug concentration is below the detectable level.
Invalid: Control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.
NOTE:

- The colour intensity of the test line (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test line region should be considered negative. Note that this is a qualitative test only, and the concentration of analytes in the specimen can not be determined.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured line appearing in the control line region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that

positive and negative controls be tested as a Good Laboratory Practice to confirm the test procedure and to verify proper test performance.
- All blood samples should be inspected further by means of other methods, e.g.: EMIT/CEDIA.
- Positive test results should be confirmed through GC-MS.

LIMITATIONS OF THE TEST

- The HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) is for in vitro diagnostic use, and should only be used for the qualitative detection of Cotinine, in blood.
- This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
- There is a possibility that technical or procedural error, as well as other substances or factors not listed may interfere with the test and cause incorrect results.
- A positive test result indicates the presence of Cotinine only.
- A negative test result does not at any time rule out the presence of Cotinine in blood, as they may be present below the minimum detection level of the test.
- This test does not distinguish between Cotinine and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy: Accuracy of the HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) was established by comparing a Whole Blood/Serum/Plasma sample against GC/MS specification. The following results were tabulated:

% Agreement with GC/MS

Specimen	COT 50
Positive	94.7%
Negative	93.8%
Total	94.2%

Analytical Sensitivity: The sensitivity of the HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) was determined by spiking a phosphate-buffered saline (serum) pool with drugs to target concentrations of +- 50% cut-off and +- 25% cut-off concentrations. The results are summarized below:

Drug Concentration (Cut-off range)	n	COT 50	
		-	+
Negative	30	30	0
50% Cut-off	30	30	0
75% Cut-off	30	30	0
Cut-off	30	4	26
125% Cut-off	30	0	30
150% Cut-off	30	0	30

Analytical Specificity: The specificity of the HOMEMED Cotinine (COT) Rapid Test Device (Whole Blood/Serum/Plasma) has been tested and the following compounds were found to produce positive results within 10 minutes, when tested at levels greater than the concentrations (in ng/ml) listed below.

Cotinine Related Compounds		Concentration (ng/ml)	
Cotinine	50	Buprenorphine	> 100 000

Non Cross-Reacting Compounds

The following compounds were found not to cross-react when tested at concentrations of 100 µg/ml:

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

LITERATURE REFERENCES

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3. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
4. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

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