

Dextromethorphan	Loperamide	Phendimetrazine
Diazepam	Loxapine succinate	Phenobarbital
Diclofenac	Maprotiline	Phenytoin
Diethylpropion	Meperidine	Phenylpropanolamine
Diflunisal	Meprobamate	Prednisolone
Digoxin	Methadone	Prednisone
Diphenhydramine	Methaqualone	Promazine
Doxylamine	Methylphenidate	Promethazine
Ecgonine hydrochloride	Methyprylon	D,L-Propanolol
β-Estradiol	Morphine-3-β-D-glucuronide	Propiomazine
Ethyl-p-aminobenzoate	Nalidixic acid	D-Propoxyphene
Fenoprofen	Nalorphine	Quinidine
Furoxime	Naloxone	Quinine
Gentisic acid	Naproxen	Salicylic acid
Glutethimide	Nifedipine	Secobarbital
Guaifenesin	Norcodein	Serotonin
Hippuric acid	Norethindrone	Sulfamethazine
Hydrochlorothiazide	Noroxymorphone	Sulindac
Hydrocodone	D-Norpropoxyphene	Temazepam
Hydrocortisone	Noscapine	Tetracycline
Hydromorphone	Nylidrin	Tetrahydrocortisone
3-Hydroxytyramine	D,L-Octopamine	Δ ⁹ Tetrahydrocannabinol-carboxylic acid
O-Hydroxyhippuric acid	Oxalic acid	Tetrahydrozoline
Ibuprofen	Oxazepam	Thebaine
Imipramine	Oxolinic acid	Thiamine
Iproniazid	Oxycodone	Thioridazine
(–) Isoproterenol	Oxymetazoline	D,L-Thyroxine
Isoxsuprine	Oxymorphone	Tolbutamide
Ketamine	Papaverine	Triamterene
Ketoprofen	Penicillin-G	Trifluoperazine
Labetalol	Pentazocaine	Trimethoprim
Levorphanol	Pentobarbital	Trimipramin
Lidocaine	Perphenazine	
	Phencyclidine	

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EC

REP

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






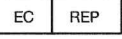


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References

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2. U.S. Department of Health and Human Services, Public Health Service, *The Health Consequences of Smoking: Cardiovascular Disease, A Report of the Surgeon General*, Rockville, MD. Office on Smoking and Health, 1983.
3. Bruckert E, Jacob N, Lamaire L, Truffert J, Percheron F, and de Gennes JL. *Relationship between Smoking Status and Serum Lipid in a Hyperlipidemic Population and Analysis of Possible Confounding Factors*. Clin Chem 1992;38:1698-1705.
4. Pojer. R, Whitfield JB, Poulos V, Eckhard IF, Richmond R, Hensley WJ. *Carboxyhaemoglobin, Cotinine and Thiocyanate Assay Compared for Distinguishing Smokers from Non-smokers*. Clin Chem 1984;30:1377-1380.
5. Benowitz NL, Kuyt F, Jacob P, et al. *Cotinine Disposition and Effects*. Clin Pharmacol Ther 34, 604-611 (1983).

Symbols Key

	Instructions For Use (Read)
	Item Number
	Store At
	Expiration Date
	Contents
	Instructions For Use
	Transfer Pipette
	For In Vitro Diagnostic Use
	Lot Number
	Manufacturer
	Manufactured For
 	Authorized Representative
	CE Mark

P-58113-F

Status DS Nicotine

One-Step Nicotine Test

For Laboratory *In Vitro* Use Only

Simple One-Step Immunoassay for the Qualitative Detection of Nicotine Metabolite in Urine

CLIA Complexity: Moderate

Stock No.	21735	35 Test Kit
	21710	10 Test Kit

Intended Use

The **Status DS Nicotine** test is a simple, one-step, immuno-chromatographic assay for the rapid, qualitative detection of cotinine, a major metabolite of nicotine, at the cut-off of 500 ng/mL in human urine. **Status DS Nicotine** is used as an aid in the detection of cotinine after use of tobacco products or other products containing nicotine. For *In vitro* Diagnostic Use

The Status DS Nicotine test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography, mass spectrometry (GC/MS) is the preferred confirmatory method.

Summary and Explanation

Smoking has been identified as a major risk factor for lung cancer and cardiovascular disease.^{1,2} Self-reporting of smoking status is not reliable.³ The detection of cotinine, a major metabolite of nicotine, has become the preferred biomedical method of assessing the smoking status of individuals on account of its sensitivity and specificity.⁴

Cotinine is present in blood, urine, and saliva of individuals who smoke or chew tobacco or who inhale tobacco smoke produced by others. As an objective indicator of nicotine intake or confirmation of nonsmoker status, cotinine offers several advantages over other biochemical measures: it is a specific indicator of nicotine intake, its concentrations are not influenced by confounding factors such as diet or environment, its average biological half-life in blood is 19 hours, and its concentration within a given individual varies by only 15 to 20% over the course of a day.⁵ Cotinine assay is thus a superior objective measure of exposure to nicotine.

Principle

The **Status DS Nicotine** test uses solid-phase chromatographic membrane immunoassay technology for a qualitative detection of a nicotine metabolite, cotinine, in human urine. The test is based on the principle of the highly specific immunochemical reactions between antigens and antibodies which are used for the analysis of specific substances in biological fluids. The test relies on the competition to bind to the antibodies between the cotinine conjugate and cotinine that may be present in the urine sample. In the test procedure, a sample of urine is placed in the Sample well of the device and is allowed to migrate upward. If cotinine is present in the urine sample, it competes with the cotinine conjugate, which is bound to the dye, for the limited antibodies immobilized on the membrane. If cotinine level is above the cutoff level, cotinine will saturate the antibodies, thus inhibiting

the binding of the dye coated with cotinine conjugate to the antibodies on the membrane. This prevents the formation of a line on the membrane. Therefore, a cotinine-positive urine sample will not generate a line at the Test position (T) in the Result window, indicating a positive result from positive cotinine competition, while a negative urine sample will generate a line at the Test position in the Result window, indicating a negative result from an absence of competition with free cotinine.

In addition to the Test line that may appear at the Test position (T), a Control line is present at the Control position (C) to confirm the viability of the test. This Control line (validation line) should always appear if the test is conducted properly. This works as a procedural control, confirming that proper sample volume was used and the reagent system at the control line and the conjugate-color indicator worked. If insufficient sample volume is used, there may not be a Control line, indicating the test is invalid.

Materials Provided

The **Status DS Nicotine** test kit contains all the reagents necessary to perform the assay.

- **Status DS Nicotine** device. The test device contains a membrane strip and a dye pad: The membrane strip is coated with monoclonal anti-cotinine antibody and the dye pad contains dye coated with cotinine-protein conjugate.
- Disposable specimen dispenser.
- Instructions for use.

Materials Needed but Not Provided

- Timer
- External positive and negative controls

Precautions

- For *in vitro* diagnostic use only.
- Avoid cross contamination of urine samples by using a new urine specimen container and dropper for each urine sample.
- Urine specimens are potentially infectious. Proper handling and disposal methods should be established according to good laboratory practices.
- The **Status DS Nicotine** device should remain in its original sealed pouch until ready for use. Do not use the test if the pouch is damaged or the seal is broken.
- Do not use the test kit after the expiration date.

Storage and Stability

The **Status DS Nicotine** test kit should be stored at 2–30°C (35–86°F) in the original sealed pouch. The expiration dating given was established under these storage conditions.

Specimen Collection and Preparation

Approximately 110 µL of urine sample is required for each test. Fresh urine specimens do not require any special handling or pretreatment. Specimens should be collected in a clean glass or plastic container. If testing will not be performed immediately, specimens should be refrigerated (2–8°C) or frozen. The stability of specimens in a refrigerator or a freezer is established up to 5 weeks. Specimens should be brought to room temperature before testing.

Specimens containing a large amount of particulate matter may give inconsistent test results. Such specimens should be clarified by centrifuging or allowing settling before testing.

