



ASAN Easy Test[®] Nicotine

Diagnostic Kit for Detection of Smoking, cotinine

Immuno-chromatography

1. INTENDED USE

The ASAN Easy Test[®] Nicotine is a lateral flow, one-step immuno-chromatographic assay for the qualitative detection of cotinine, the major metabolite of nicotine in human urine, at a cut-off concentration 200 ng/ml.

2. EXPLANATION OF THE TEST

Tabacco smoking results in the absorption of nicotine through the lung and nasal epithelium, after which nicotine is metabolized into about 20 metabolites excreted in urine. Cotinine, a major metabolite, accumulates in the body with regular smoking. The half-life of cotinine is about 20 hours and its concentration in the urine reflects exposure to tobacco smoke during the past few days prior to specimen collection.

3. PRINCIPLE OF THE TEST

The ASAN Easy Test[®] Nicotine is the *in vitro* diagnostic kit to qualitatively detect a nicotine metabolite, cotinine in human urine using the technology of solid-phase immuno-chromatographic assay. The principle of the test is highly specific immunoreaction between antigen and antibody, which is used for the analysis of specific substances in specimens. Each test device constitutes nitrocellulose membrane pre-immobilized with cotinine-ova complex on the test line, and the conjugate pad containing mouse anti-cotinine monoclonal antibody-gold conjugate is partially overlapped between the sample pad and the membrane. In the absence of the cotinine in the urine, the specimen solution applied into the sample well migrates chromatographically by the capillary action toward the absorbance pad. In the test line zone, the antibody-gold conjugate interacts with the immobilized cotinine-ova complex and then forms a visible line. When the level of cotinine is below or above the cutoff concentration, the cotinine competes with cotinine-ova conjugates on the test line for binding to the limited antibody on the gold colloidal. If a sufficient concentration is present (above the cutoff) in the sample, the cotinine will bind the limited antibody in advance, which prevent the binding of the colorized antibody-gold conjugate to the cotinine-ova complex in the test zone. At the control region, the band is formed by another antigen-antibody interaction to indicate that the test has been performed properly.

4. MATERIALS PROVIDED

The ASAN EASY TEST Anti-HBs Strip kit contains following items to perform the assay.

- 1) The device in aluminum pouch with a desiccant.
- 2) Disposable droppers.
- 3) Instructions manual for use

5. PRECAUTIONS

- 1) For in vitro diagnostic use only.
- 2) For professional use only.
- 3) Urine specimens are potentially infectious. Proper handling and disposal methods should be established according to good laboratory practices.
- 4) Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.
- 5) Do not use the test kit after the expiration date.

6. SPECIMEN COLLECTION AND PREPARATION

The ASAN Easy Test[®] Nicotine is formulated for use with urine specimens. Fresh urine specimens do not require any special handling or pretreatment. Specimens should be collected in a clean glass or plastic container. The specimen may be refrigerated at 2 - 8 °C for 1-2days or frozen for a longer period. Specimens should be thawed and equilibrated to room temperature before test.

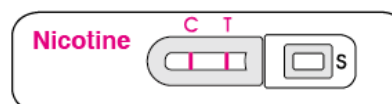
7. TEST PROCEDURE

Testing is performed by two steps, adding the sample to the Sample well and observing the appearance of color band.

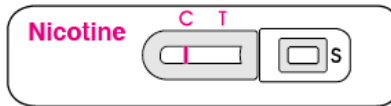
- 1) Equilibrate test device and specimens to room temperature.
- 2) Open Easy Test Nicotine pouch and label the device with the patient ID.
- 3) Dispense 3 drops of the urine specimen into Sample well.
- 4) Read the result in 4-10 minutes.

7. INTERPRETATION OF THE TEST

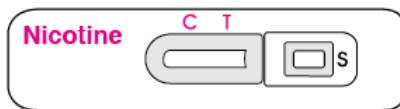
- 1) Negative: Two color band appear at the Control region (C) and the Test region (T), which indicates a negative test result (i.e., no cotinine above the cut-off level has been detected) The color intensities of the Test line may be weaker or stronger than that of the Control line.



2) Positive: One color band appears at the Control region (C), which indicates a positive test result (i.e., the specimen contains cotinine at a concentration above the cut-off level).



3) Invalid: No line appears in the control region, which indicates that the test is invalid. The test result is inconclusive and the tests should be repeated with a new Easy Test Nicotine test device.



※ *A negative test result does not indicate the absence of cotinine in the sample. It only indicates the sample does not contain cotinine above the cutoff level in qualitative terms. And also, a positive test result does not provide any indication of the level of intoxication or urinary concentration of the cotinine in the sample. It only indicates the sample contains cotinine above the cutoff level in qualitative terms.*

8. QUALITY CONTROL

It is recommended that the use of control reagents ensure proper kit performance according to good laboratory practices. Quality control specimens are easily available from commercial sources. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

9. STORAGE & EXPIRATION

- 1) The Asan Easy Test Nicotine should be stored at room temperature 2~30°C.
- 2) Expiration date of this kit is 24 months after its manufacture date.

10. LIMITATIONS

- 1) The test is designed for use with human urine only.
- 2) There is a possibility that technical or procedural errors as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.
- 3) The test must be read within 10 minutes of sample application. The test result read after 10 minutes may not be consistent with the original reading

- obtained within the 10 minute reading period.
- 4) If it is suspected that the samples have been mislabeled or tampered with, a new specimen should be collected and the test should be repeated.



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