One Step THC Screen Test (Urine)

【INTENDED USE】

The product is a one -step test for the qualitative detection of 11-nor-Δ9-THC-9-COOH（THC）in human urine at a cut-off level of 50ng/ml. It is for professional use.

The test device will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

【SUMMARY】

THC (Δ9--tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary
metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid (Δ9-THC-COOH).

The One StepCOC/THC Screen Test (Urine) yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

【PRINCIPLE】

This assay is a one-step lateral flow chromatographic immunoassay.The test strip includes 1)aburgundy -colored conjugate pad containing mouse anti-Marijuana (THC) antibodies coupled to colloidal gold;2)nitrocellulose membrane containing a Test (T) line and a Control（C） line. The Test line is coated with Marijuana (THC)-BSA,and the Control line is coated with goat anti-mouse IgG antibody.

The test device is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the device has been performed properly.

【MATERIALS】

Each package contains:

• Test devices • Package insert • Dropper (for cassette)

Materials required but not provided

• Specimen collection container • Timer

【PRECAUTIONS】

1.For medical and other professional in vitro diagnostic use only.
2.Do not use after the expiration date indicated on the package.
3.Do not use the test device if the foil pouch is damaged.
4.The test device is for one time use only; it is not reusable.
5.The test device should remain in its original sealed pouch until use.
6.Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.

【STORAGE AND STABILITY】

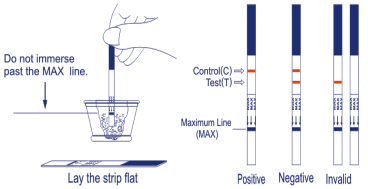
1.Store as packaged in the sealed pouch at 2-35°C.
2.The test device is stable through the expiration date printed on the sealed pouch.
3.DO NOT FREEZE.

【SPECIMEN COLLECTION AND STORAGE】

1.The urine specimen must be collected in a clean and dry container.
2.Urine collected at any time of the day may be used.
3.Fresh urine does not require any special handling or pretreatment.
Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
4.It is recommended the collected fresh urine to be tested immediately. Urine specimens may be stored at 2-8°C for up to 72 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

【TEST PROCEDURE】

Allow the test panel, urine specimen, and/or controls to equilibrate to room temperature (10-30°C)prior to testing.

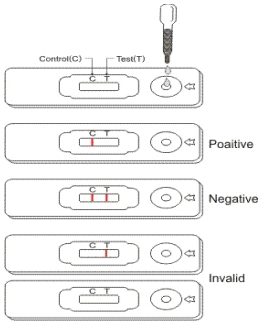


•STRIP

(1) Remove the test device from the sealed foil pouch.
(2)With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10 seconds.
(3)Place the strip on a non-absorbent flat, dry surface.
(4) Read the result within 5-10 minutes.

•CASSETTE

(1)Remove the test device from the sealed foil pouch and place it on a dry, flat surface.
(2)Using the specimen dropper, withdraw the urine sample from the specimen cup and slowly dispense 2 drops into the circular sample well. Start the timer.
(3)Read the result within 5-10 minutes.



【INTERPRETATION OF RESULTS】

1. Positive (+) : A red line is visible in control region(C). No color line appears in test region (T). This indicates that the drug concentration in the urine specimen exceeds the designated detection limit for that specific drug.
2. Negative (-) : A red line is visible in both control region(C) and the test region (T). This indicates that the drug concentration in the urine specimen is below the designated detection limit level for that specific drug.
3. Invalid: If a color line is not visible in control region(C), the test result is invalid. Another test device should be run to re-evaluate the specimen. If the problem persists, discontinue using the device immediately and contact your local distributor.

【QUALITY CONTROL】

1.Built-in Control Features: A procedural control is included in the test device. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
2.External Quality Control: Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1.The assay is designed for use with human urine only..
2.The test device is a screening device; it does not detect the actual concentration of a drug.
3.The test device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
4.There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
5.Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the device should be repeated with another urine specimen.
6.A positive result does not indicate level or intoxication, administration route or concentration in urine.
7.A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the device.
8.If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and medicines.

【PERFORMANCE CHARACTERISTICS】

1.**Analytical Sensitivity:**
Standard drugs were spiked into negative urine samples to the concentration of -50% cut-off, -25% cut-off, cut-off, +25% cut-off and +50% cut-off. The results were summarized below.

Marijuana (THC)Conc.(Cut-off range)	n	Negative −	Positive +
0% Cut-off	20	20	0
-50% Cut-off	20	20	0
-25% Cut-off	20	20	0
Cut-off	20	0	20
+25% Cut-off	20	0	20
+50% Cut-off	20	0	20

2.Accuracy
A comparison was conducted using each of the test devices and commercially available drug rapid test (the predicate kits). Approximately 300 specimens were used in the device. Positive results were confirmed by GC/MS. The results were listed as follows:

	%Agreement with GC/MS	%Agreement with Commercial Kit
Positive	97%	100%
Negative	98%	100%

3. Analytical Specificity
The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the One Step THC Test (Urine) at 5 minutes.

MARIJUANA (THC)Compound	Concentration
11-nor-Δ8-THC-9-COOH	50ng/mL
11-nor-Δ9-THC-9-COOH	50ng/mL
Δ8-Tetrahydrocannabinol	20,000ng/mL
Δ9-Tetrahydrocannabinol	20,000ng/mL

4.Interference
An unaltered sample was used as a control. No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 μg/ml.

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid	Imipramine (Except TCA)
(+)-Naproxen	Creatine	Penicillin-G	(+/-)-Isoproterenol
(+/-)-Ephedrine (Except MET)	Dextromethorphan	Pheniramine	Lidocaine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	Phenothiazine	Vitamin C

Acetaminophen (Except ACE)	Dopamine	L-Phenylephrine	Trimeprazine
Acetone	Erythromycin	Procaine	Venlafaxine
Albumin	Ethanol	Protonix	Tyramine
Amitriptyline (Except TCA)	Furosemide	Pseudoephedrine	Ibuprofen
Ampicillin	Glucose	Quinidine	Benzocaine
Aspartame	Guaiacol Glyceryl Ether	Ranitidine	Bilirubin
Aspirin	Hemoglobin	Sertraline	b-Phenylethyl-amine
Atropine	Methadone (Except MTD)	Caffeine	Secobarbital
Ketamine（KET）	3,4-Methylenedioxy-MET	Methamphetamine	Morphine
Benzoylecgonine	Amphetamine	Cocaine	

【BIBLIOGRAPHY】

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA2002.
2. Hardman J, Limbird LE (Eds), Goodman & Gilman's The Pharmacological Basis of Therapeutics,10th edition, McGraw-Hill Publishing, 2001; p. 598
3. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.

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Index of Symbol			
	Manufacturer		Temperature limit
EC REP	Authorized representative in the European Community		Do not re-use
	Use-by date		Caution
LOT	Batch code		Consult instructions for use
REF	Catalogue number Indicates	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests		