Asan EasyTest® DOA-6

For MET/THC/MOR/AMP/COC/MDMA

Immunochromatography

INTENDED USE

Asan Easy Test DOA-6 is an one-step immuno-chromatographic assay intended for simultaneous qualitative detection of methamphetamine, 11-nor-delta-9- tetrahydrocannabinol -9-carboxylic acid (THC), morphine, amphetamine, cocaine (benzoylecgonine), MDMA (methylenedioxymethamphetamine, Ecstasy) in human urine with the following cutoff concentrations.

MET	Methamphetamine	1000 ng/ml
THC	11-nor-delta-9-THC-9-COOH	50 ng/ml
MOR	Morphine	300 ng/ml
AMP	Amphetamine	1000 ng/ml
COC	Benzoylecgonine	300 ng/ml
MDMA	(+/-)3,4-MDMA	500 ng/ml

EXPLANATION OF THE TEST

Asan Easy Test DOA-6 is the in vitro diagnostic kit to qualitatively detect the drug 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 drug-protein complex on the test line, and the conjugate pad containing mouse anti-drug monoclonal antibody-gold conjugate is partially overlapped between the sample pad and the membrane. In the absence of the drug 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 drug-protein complex and then forms a visible line. When the level of drug is below or above the cutoff concentration, the drug antigen competes with drug-protein 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 drug will bind the limited antibody in advance, which prevent the binding of the colorized antibody-gold conjugate to the drug-protein conjugate in the test zone. At the control region, the band is formed by another antigen-antibody interaction to indicate that the test has performed properly.

MATERIALS PROVIDED

Asan Easy Test DOA-6 test kit contains the following items:

1) Test device individually foil-pouched with a desiccant: 10ea
2) Disposable dropper: 10ea
3) Instruction manual for use.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Urine specimens are potentially infectious, Proper handling and disposal methods should be established in accordance with GLP.
5. Avoid cross-contamination of urine samples by using new specimen collection container and dropper for each urine sample.
6. Do not use the test kit after the expiration date.

SPECIMEN COLLECTION AND STORAGE

Asan Easy Test DOA-6 is formulated for use with urine specimens.

1. Fresh urine specimens do not require any special handling or pretreatment.
2. Specimens should be collected in a clean glass or plastic container.
3. The specimen may be refrigerated at 2 - 8℃ for 1 - 2 days or frozen for a longer period.
4. Specimens should be thawed and equilibrated to room temperature before test.
5. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
3. Record patient's details(name, ages and date) on device.
4. [Using a disposable urine dropper]
   With a disposable dropper, add 3 drops (about 100-120㎕) of urine specimen into 5 each sample wells.
   [Dipping method]
   Hold the test device vertically and immerse it into the urine specimen for 10 seconds. After 10 seconds, Remove from the urine specimen.
   CAUTION: When immersing the test device, insert to MAX. urine level.
5. Interpret test results at 10minutes. Do not interpret test result after 10minutes.

INTERPRETATION OF THE RESULTS

(1) Negative: Two colorized lines appear at the control region (C) and the test region (T or T1/T2), which indicates a negative test result (i.e., no drug 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 colorized lines appears at the control region (C), which indicates a positive test result (i.e., the specimen contains drug 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 test device.

* A negative test result does not indicate the absence of drug in the sample. It only indicates the sample does not contain drug 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 drug in the sample. It only indicates the sample contains drug above the cutoff level in qualitative terms.

QUALITY CONTROL

It recommends 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.

LIMITATIONS OF THE TEST

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 5 minutes of sample application. The test result read after 5 minutes may not be consistent with the original reading obtained within the 5 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.

STORAGE & EXPIRATION

1. Asan Easy Test DOA-6 should be stored at refrigerated or at room temperature 1 - 30℃ (33.8~86˚F) in the original sealed pouch. The noted expiration date was established under these storage condition.

2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

1. Precision and accuracy

The accuracy of Asan Easy Test DOA-6 was evaluated in comparison to a commercially available immunoassay. One hundred (100) urine samples, collected from presumed non-user volunteers and Korean Doping Control Center, have been tested by both methods. Of these urine specimens tested, all were found negative by both methods (100% agreement on negative samples). And one hundred (100) urine samples for each of ten specific drugs, obtained from a clinical laboratories where the drug samples were prepared by spiking each drug of which concentrations were previously determined by GC/MS, were tested with Asan Easy Test DOA-6 and a commercially available immunoassay. The results are listed below:

Drug	Concentration (ng/ml)	Commercial Kit # of positive : # of negative	Asan Easy Test DOA-6 # of positive : # of negative
Methamphetamine[MET]	500	0:20	0:20
	750	0:20	0:20
	1000	-	17:3
	1250	20:0	20:0
	1500	20:0	20:0
11-nor-delta-9-THC-9	25	0:20	0:20
-COOH [THC]	37.5	0:20	0:20
	50	-	17:3
	62.5	20:0	20:0
	75	20:0	20:0
Morphine[MOR]	150	0:20	0:20
	225	1:19	0:20
	300	12:8	15:5
	375	20:0	20:0
	450	20:0	20:0
Amphetamine[AMP]	500	0:20	0:20
	750	0:20	0:20
	1000	-	18:2
	1250	20:0	20:0
	1500	20:0	20:0
Benzoylecgonine[COC]	150	0:20	0:20
	225	1:19	0:20
	300	-	5:15
	375	20:0	20:0
	450	20:0	20:0
(+/-)3,4-MDMA[MDMA]	250	-	0:20
	375	-	0:20
	500	-	15:5
	625	-	20:0
	750	-	20:0

2. Reproducibility

The reproducibility of Asan Easy Test DOA-6 was evaluated at three different sites, testers, routs using the controls.

3. Specificity

The secificity for EasyTest DOA-6 was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine. The following structurally related compounds produce positive results when tested at levels equal to or greater than the concentrations listed below.

Compound	Conc. ng/ml
Asan Easy Test MET	
d-Methamphetamine	1,000
d-Amphetamine	>100,000
Chloroquine	>100,000
(+/-)-Ephedrine	2,500
(+/-)3,4-MDA	>100,000
(+/-)3,4-MDMA	2,000
Procaine	10,000
Phenylethylamine	50,000
Ranitidine	50,000
Asan Easy Test THC	
11-nor-delta--9-THC-9-COOH	50
11-Hydroxy-Tetrahydrocannabinol	5,000
9-Tetrahydrocannabinol	10,000
Cannabinol	>20,000
Cannabidiol	>100,000
Asan Easy Test MOR	
Morphine	300
Codeine	300
Ethyl morphine	300
Hydrocodone	375
Hydromorphine	400
Meperidine	75,000
Morphine-3-beta-d-glucuronide	375
Norcodeine	30,000
Thebaine	30,000

Compound	Conc. ng/ml
Asan Easy Test AMP	
d-Amphetamine	1,000
l-Amphetamine	20,000
(+/-)3,4-MDA	1,750
(+/-)3,4-MDMA	4,000
Tyramine	70,000
Asan Easy Test COC	
Benzoylecgonine	300
Cocaine	300
Ecgonine	>10,000
Compound	Conc. ng/ml
Asan Easy Test MDMA	
(+/-)3,4-MDMA	300
d-Methamphetamine	1,000
d-Amphetamine	>100,000
Chloroquine	>100,000
(+/-)-Ephedrine	2,500
(+/-)3,4-MDA	>100,000

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

Acetone	Benzocaine	Sulindac
Hemoglobin	(+)-Naproxen	(+)-Ephedrine
Acetaminophen	Bilirubin	Thioridazine
Imipramine	(+/-)-Norephedrine	(-)-Ephedrine
Albumin	Caffeine	Trimethobenzamide
(+/-)-Isoproterenol	Oxalic Acid	(+)-Epinephrine
Amitriptyline	(+)-Chlorpheniramine	Vitamin C
Lidocaine	Penicillin-G	Erythromycin
Ampicillin	(+/-)-Chlorpheniramine	Trifluoperazine
(1R,2S)-(-)-N-methyl -ephedrine	Pheniramine	Ethanol
Aspartame	Creatine	Furosemide
Naloxone	Phenothiazine	Glucose
Aspirin	Dextromethorphan	Guaiacol Glyceryl Ether
Natrexone	Quinidine	
Atropine	Dimethylaminoantipyrine	
Naphthalena acetic acid	Sodium Chloride	
	Dopamine	

REFERENCES

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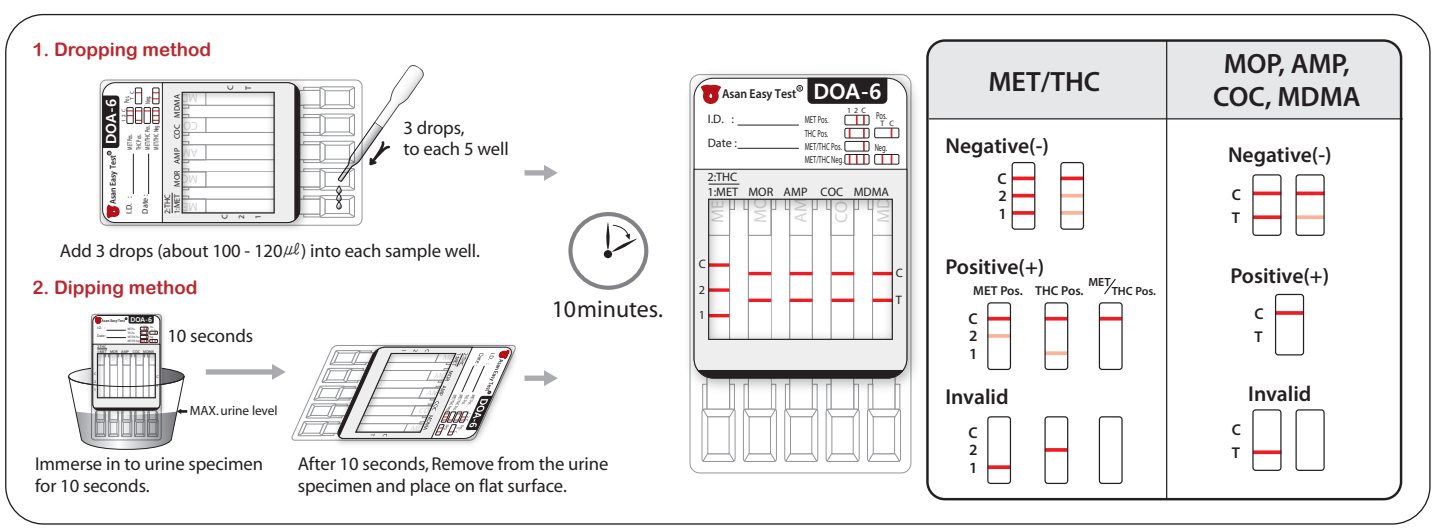

Manufactured by
ASAN PHARMACEUTICAL CO., LTD
122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, 17551, Korea
Tel: +82-31-376-5990~2
Fax: +82-31-376-5993
http://www.asanpharm.com

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