Asan EasyTest® DOA-Individual

For MOR, AMP, MET, THC, COC, MDMA, MTD, PCP, BAR, BZO

Immunochromatography

INTENDED USE

Asan EastTest DOA-Individual is an one-step immuno-chromatographic assay intended for use in the qualitative detection of morphine, amphetamine, methamphetamine, 11-nor-delta-9-tetrahydrocannabinol -9-carboxylic acid (THC), benzoylecgonine, MDMA, methadone, phencyclidine, barbiturates and benzodiazepine in human urine with the following cutoff concentrations.

MOR	Morphine	300 ng/ml
AMP	Amphetamine	1000 ng/ml
MET	Methamphetamine	1000 ng/ml
THC	11-nor-delta-9-THC-9-COOH	50 ng/ml
COC	Benzoylecgonine	300 ng/ml
MDMA	(+/-)3,4-MDMA	500 ng/ml
MTD	Methadone	300 ng/ml
PCP	Phencyclidine	25 ng/ml
BAR	Secobarbital	300 ng/ml
BZO	Oxazepam	300 ng/ml

EXPLANATION OF THE TEST

Asan EasyTest DOA-Individual 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

EasyTest DOA-Individual test kit contains

1) Individually foil-pouched test devices
2) Disposable dropper
3) Instruction manual for use.

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 new specimen collection container and specimen pipette for each urine sample.
5. Do not use the test kit after the expiration date.

TEST PROCEDURE

1. Specimen collection and preparation

EasyTest DOA-Individual 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℃ for 1 - 2 days or frozen for a longer period. Specimens should be thawed and equilibrated to room temperature before test.

2. Test protocol

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

(1) Equilibrate test device and specimens to room temperature prior to testing (~15minute).

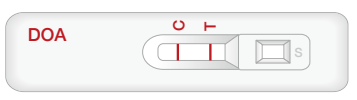
(2) Open EasyTest DOA pouch and label the device with the patient's ID.

(3) Dispense 3 drops of the urine specimen into Sample well.

(4) Read the result in 4 - 10 minutes.

INTERPRETATION OF THE RESULTS

(1) Negative: Two colorized lines appear at the control region (C) and the test region (T), 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 EasyTest Drug 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.

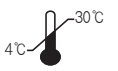
(2) There is a possibility that technical or procedural errors as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.

(3) The test must be read within 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.

STORAGE & EXPIRATION

1. The EasyTest DOA-Individual should be stored at refrigerated or at room temperature 4 - 30℃ (39~86°F) in the original sealed pouch. The noted expiration date was established under these storage condition.



2. Expiration date of this kit is 18 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

1. Precision and accuracy

The accuracy of EasyTest DOA-Individual 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 EasyTest Drug Individual. and a commercially available immunoassay. The results are listed below:

Drug	Concentration (ng/ml)	Commercial Kit # of positive : # of negative	Asan EasyTest DOA # of positive : # of negative
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
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 -COOH [THC]	25	0:20	0:20
	37.5	0:20	0:20
	50	-	17:3
	62.5	20:0	20:0
	75	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
Methadone[MTD]	150	0:20	0:20
	225	0:20	0:20
	300	-	16:4
	375	20:0	20:0
	450	20:0	20:0
Phencyclidine[PCP]	12.5	0:20	0:20
	18.75	0:20	0:20
	25	-	17:3
	31.25	20:0	20:0
	37.25	20:0	20:0
Secobarbital[BAR]	150	0:20	0:20
	225	0:20	0:20
	300	-	17:3
	375	20:0	20:0
	450	20:0	20:0
Oxazepam[BZO]	150	0:20	0:20
	225	0:20	0:20
	300	-	18:2
	375	20:0	20:0
	450	20:0	20:0

2. Reproducibility

The reproducibility of EasyTest DOA-Individual was evaluated at three different sites, testers, routs using the controls.

3. Specificity

The secificity for EasyTest DOA- Individual 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 EasyTest 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
Asan EasyTest AMP	
d-Amphetamine	1,000
l-Amphetamine	20,000
(+/-)3,4-MDA	1,750
(+/-)3,4-MDMA	4,000
Tyramine	70,000
Asan EasyTest 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 EasyTest 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 EasyTest COC	
Benzoylecgonine	300
Cocaine	300
Ecgonine	>10,000

Compound	Conc. ng/ml
Asan EasyTest MDMA	
(+/-)3,4-MDMA	300
d-Methamphetamine	1,000
d-Amphetamine	>100,000
Chloroquine	>100,000
(+/-)-Ephedrine	2,500
(+/-)3,4-MDA	>100,000
Asan EasyTest MTD	
Methadone	300
alpha-Methadol	>500
2-Ethylidere-1,5-dimethyl-3,3-diphen-ylpyrolidire	50,000
Asan EasyTest PCP	
Phencyclidine	
Tenocyclidine	2,000
Asan EasyTest BAR	
Secobarbita	300
Butabarbital	>1,000
Phenobarbital	1,750
Amobarbital	>2,000
Butalbital	1,500
Phentobarbital	>1.000
Asan EasyTest BZO	
Oxazepam	300
Alprazolam	150
Bromazepam	800
Clobazam	200
Clonazepam	25,000
Chlordiazepoxide	300
Estazolam	300
Flurazepam	300
Nordiazepam	150
Temazepam	150

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

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

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