P-5862-C

AccuSign® *DOA 7*

THC/OPI/COC/MET/ BZO/MTD/AMP

New One-Step Panel Assay for Drugs of Abuse

For *In Vitro* Use Only

Simple One-Step Immunoassay for the Qualitative Detection of THC, Opiates, Cocaine, Methamphetamine, Benzodiazepines, Methadone, Amphetamine and/or their Metabolites in Urine

PBM

Catalog No.	DOA-270-35	35 Test Kit
	DOA-270-10	10 Test Kit

Intended Use

The **AccuSign® *DOA 7*** *THC/OPI/COC/MET/BZO/MTD/AMP* Panel Assay is a simple, one-step immunochromatographic test for the rapid, qualitative detection of THC, opiates, cocaine, methamphetamine, benzodiazepines, methadone, and amphetamine and/or their metabolites in urine.

The* AccuSign® DOA 7 THC/OPI/COC/MET/BZO/MTD/AMP *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. Other chemical confirmatory methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.[1]

Summary and Explanation

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When ingested or smoked, it produces euphoric effects. Users experience impairment of short term memory and THC use slows learning. Also, it may cause transient episodes of confusion, anxiety, or frank toxic delirium. Long term, relatively heavy use may be associated with behavioral disorders. The peak effect of smoking THC 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-Δ^9-tetrahydrocannabinol-9-carboxylic acid.[2]

Morphine, codeine, and semisynthetic derivatives of morphine belong to the class of drugs called opiates. An opiate exerts its effects on the central nervous system and can produce euphoria, respiratory depression and coma when it is abused. Morphine is the prototype compound of opiates. Morphine is excreted in the urine as morphine-3-glucuronide, unchanged morphine, and other minor metabolites. Heroin is metabolized to morphine and codeine and excreted in the urine with a small amount in unchanged form. Codeine is also excreted as morphine and in the form of conjugates. Although some opiate metabolites appear in the feces, urinary excretion is the primary route of elimination.[1,2,4]

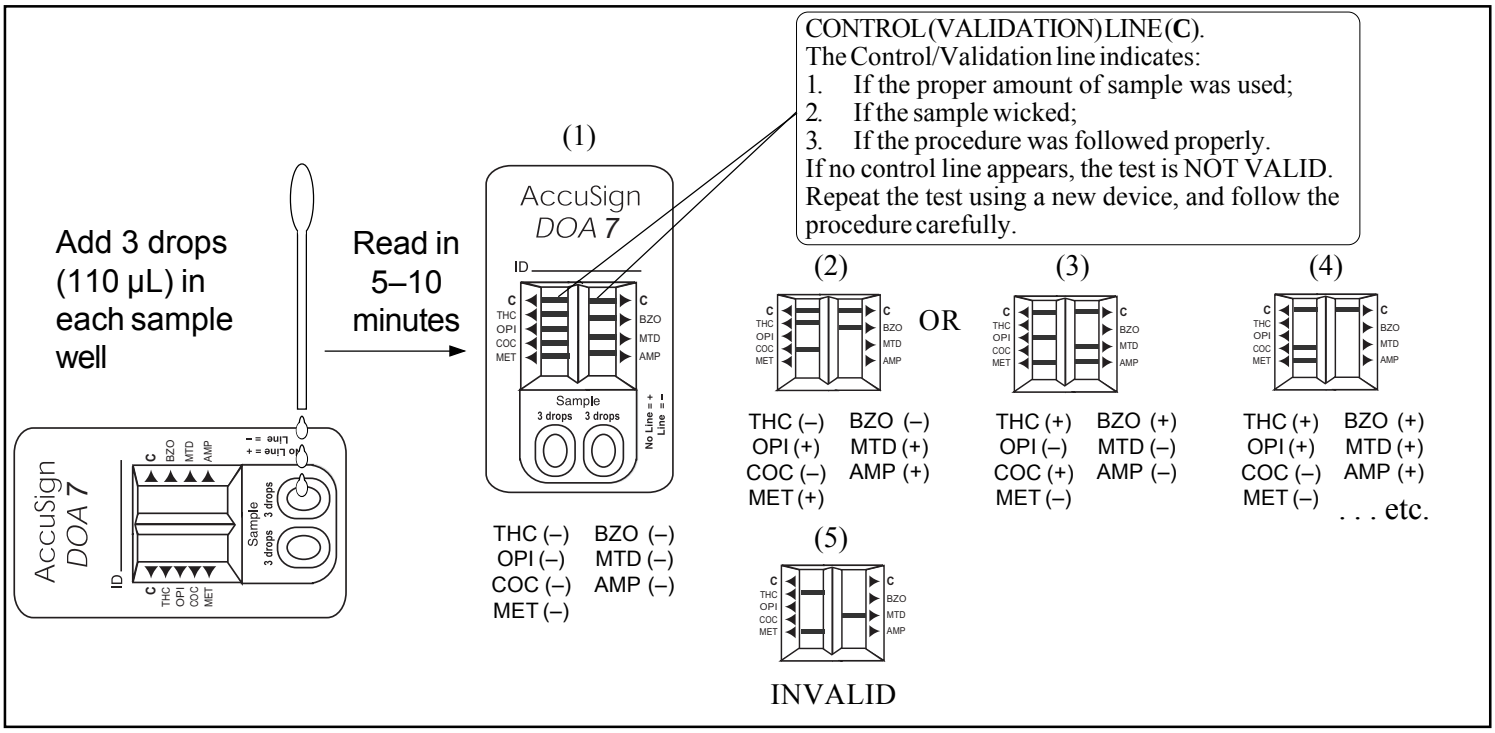
Cocaine, derived from the leaves of coca plant, is a potent central nervous system (CNS) stimulant and a local anesthetic. Cocaine induces euphoria, confidence and a sense of increased energy in the user; these psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is used by smoking, intravenous, intranasal or oral administration, and excreted in the urine primarily as benzoylecgonine in a short time. Benzoylecgonine has a longer biological half-life (5–8 hours) than cocaine (0.5–1.5 hours) and can generally be detected for 24–60 hours after cocaine use or exposure.[3,4]

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses include anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of methamphetamine generally last 2–4 hours, and the drug has a half-life of 9–24 hours in the body. Methamphetamine is excreted in the urine primarily as amphetamine and oxidized and deaminated derivatives. However, 10–20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. Methamphetamine is generally detectable in the urine for 3–5 days, depending on urine pH level.[4]

Benzodiazepines are a class of widely prescribed central nervous system (CNS) depressants and include widely used drugs such as chlordiazepoxide, diazepam, and oxazepam. They have medically useful properties, including antianxiety, sedative, anticonvulsant, and hypnotic effects. They are taken orally or sometimes by injection, and have a low potential for physical or psychological dependence. Benzodiazepines induce drowsiness and muscle relaxation; however, their use can also result in intoxication, similar to drunken behavior except without evidence of alcohol use, and the loss of inhibitions. Chronic abuse can result in addiction and tardive dyskinesia (involuntary muscle movements of the face, limbs, and trunk). Overdose can result in coma and possible death. Withdrawal syndrome includes anxiety, insomnia, tremors, delirium, and convulsions. The effects of benzodiazepine use last 4–8 hours. The different benzodiazepines are absorbed at different rates, and the timing of their psychoactive effects varies with the absorption rate. The drugs are excreted in the urine primarily as the parent compounds or as oxazepam glucuronide, an inactive metabolite, (in the case of chlordiazepoxide and diazepam) and are detectable for 1–2 days. Oxazepam may be detectable in the urine for up to 7 days. [2,3]

Methadone is a synthetic analogic drug which possesses many of the pharmacologic properties of morphine. Unlike morphine, however, methadone produces marked sedative effects with repeated administration as a result of drug accumulation. Overdosage with methadone is characterized by stupor, muscle flaccidity, respiratory depression, cold and clammy skin, pupillary constriction, hypotension, coma and circulatory collapse. Fatalities in adults from methadone overdosage have increased significantly in many urban areas as a result of widespread availability of the drug, both from licit and illicit sources.[2,3]

Amphetamine is a potent sympathomimetic agent with therapeutic applications. It is chemically related to the human body's natural catecholamines, epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses include anxiety, paranoia, hallucinations, and psychotic behavior. Amphetamine is largely inactivated during metabolism, being deaminated to phenylacetone which is subsequently oxidized to benzoic acid and excreted as conjugates. However, a small amount is converted by oxidation to norephedrine, and this compound and its parent are p-hydroxylated. Probably the entire dose of amphetamine is eliminated from the urine over a period of several days; normally about 30% is excreted unchanged in the 24-hour urine, but this may increase to as much as 74% in acid urine and may decrease to 1% in alkaline urine. Under normal conditions 0.9% is excreted as phenylacetone, 16-28% as hippuric acid, 4% as benzoylglucuronide, 2% as norephedrine, 0.3% as conjugated p-hydroxynorephedrine, and 2-4% as conjugated p-hydroxyamphetamine.[2, 5]



Principle

The **AccuSign**® ***DOA 7*** test uses solid-phase chromatographic membrane immunoassay technology for the qualitative, simultaneous detection of THC, opiates, cocaine, methamphetamine, benzodiazepines, methadone, and amphetamine 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 between the drug conjugates and the drugs which may be present in the urine sample, for binding to antibodies. In the test procedure, a sample of urine is placed in the Sample well of the device and is allowed to migrate upward. If the drug is present in the urine sample, it competes with the drug conjugate bound to the dye, for the limited antibodies immobilized on the membrane. If the level of drug or drug metabolite is above the cutoff level, the drug will saturate the antibodies, thus inhibiting the binding of the dye coated with drug conjugates to the antibodies on the membrane. This prevents the formation of a line on the membrane. Therefore, a drug-positive urine sample will not generate a line at the specific drug position in the Result window, indicating a positive result. A negative urine sample will generate a line at the specific drug position in the Result window, indicating a negative result. The same principle of competition is applicable where the drug conjugate is immobilized on the membrane and the antibody is coated on the dye.

In addition to the Test line(s) that may appear in the Result window, a Control line is present to confirm the viability of the test. This Control line (validation line) should always appear if the test is conducted properly. Polyclonal sheep anti-mouse IgG antibody is immobilized on the control line. The monoclonal antibody-dye conjugates that pass the line will be captured and produce a colored line at the Control position (C). 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 properly. If insufficient sample volume is used, there may not be a Control line, indicating the test is invalid.

Materials Provided

The **AccuSign**® ***DOA 7*** test kit contains all the reagents necessary to perform the assay.

- **AccuSign**® ***DOA 7*** device. The test device contains a membrane strip and a dye pad. Membrane strips are coated with THC-protein (a purified bovine protein) conjugate, monoclonal anti-morphine, anti-benzoylecgonine, anti-methamphetamine, anti-methadone, and anti-amphetamine antibodies as well as polyclonal anti-benzodiazepine antibody. Sheep anti-mouse antibody is coated for the control band. Dye pads contain colloidal gold coated with monoclonal anti-THC antibody as well as conjugates of morphine, benzoylecgonine, methamphetamine, oxazepam, methadone, and amphetamine (each drug is conjugated with a purified bovine protein).
- Disposable sample dispenser.
- Instructions for use.

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.
- This test kit does not contain any HIV or hepatitis infective components.
- Urine specimens are potentially infectious. Proper handling and disposal methods should be followed, according to good laboratory practices.
- The **AccuSign**® device should remain in its original sealed pouch until ready for use.
- Do not use the test kit after the expiration date.

Storage and Stability

The **AccuSign**® ***DOA 7*** test kit should be stored at 2–30°C (35–86°F) in the original sealed pouch. The expiration dating was established under these storage conditions.

Specimen Collection and Preparation

Approximately 110 µL of urine sample is required for each test sample well. 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. Frozen specimens must be completely thawed, and thoroughly mixed before using.

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

Test Procedure

The test procedure consists of adding the urine sample to each of two Sample wells of the device and watching for the appearance of colored lines in both result windows.

Test Protocol

1. For each test, open one **AccuSign®** ***DOA 7*** pouch and label the device with the patient ID.
2. Holding the dropper vertically, dispense 3 full drops (110 µL) of the urine sample into each Sample well.
3. Read the result after 5 minutes, but within 10 minutes.

Interpretation of Results

Negative: The appearance of a reddish-purple Control line (**C**) and a line for a specific drug indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and a specific drug line may not be equal. *Any faint line at a specific drug name in the Result window, visible in 10 minutes, should be interpreted as negative. 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.*

Positive: The appearance of a reddish-purple Control line and no distinct line at a specific drug name indicates the test result is positive for that drug (i.e., the specimen contains the drug at a concentration above the cutoff level). *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.*

Invalid: A distinct Control line (**C**) should always appear. The test is invalid if no Control line forms at the **C** position. Such tests should be repeated with a new **AccuSign®** ***DOA 7*** test device.

Examples of possible results are shown in the diagram in page 2.

(1) **THC (–), Opiates (–), Cocaine (–), Methamphetamines (–), Benzodiazepines (–), Methadone (–), Amphetamine (–)**: Nine reddish-purple lines—one line each at the **C** positions and one each at the **THC**, **OPI**, **COC, MET, BZO, MTD,** and **AMP** positions.

(2) **THC (–), Opiates (+), Cocaine (–), Methamphetamines (+), Benzodiazepines (–), Methadone (+), Amphetamine (+)**: Five reddish-purple lines—one line each at the **C** positions and one line each at the **THC**, **COC** and **BZO** positions; no line at the **OPI, MET, MTD,** and **AMP** positions.

(3) **THC (+), Opiates (–), Cocaine (+), Methamphetamines (–), Benzodiazepines (+), Methadone (–), Amphetamine (–)**: Six reddish-purple lines—one line each at the **C** positions and one line each at the **OPI**, **MET, MTD** and **AMP** positions; no line at the **THC, COC,** and **BZO** positions.

(4) **THC (+), Opiates (+), Cocaine (–), Methamphetamines (–), Benzodiazepines (+), Methadone (+), Amphetamine (+)**: Four reddish-purple lines—one line each at the **C** positions and one line each at the **COC** and **MET** positions; no line at the **THC, OPI, BZO, MTD,** and **AMP** positions.

(5) **Invalid**: No line at the C position.

There are other possible results, depending on the combinations of drugs present in the urine sample.

Limitations

- The test is designed for use with unadulterated urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine sample than those listed in Table 12 below, may interfere with the test and cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, the test should be repeated with a new sample.
- The test result read after 10 minutes may not be consistent with the original reading obtained within the 10 minute reading period. The test result must be read within 10 minutes of sample application.
- Certain medications containing opiates or opiate derivatives or methamphetamines may produce a positive result. Additionally, foods and tea containing poppy products and/or coca leaves may produce a positive result. Prolonged passive smoking of THC may also produce a positive result.

User Quality Control

Internal Control: Each **AccuSign®** ***DOA 7*** test device has a built-in control. The Control line is an internal positive procedural control. A distinct reddish-purple Control line should appear in the Control position, if the test procedure is performed properly, an adequate sample volume is used, the sample and reagent are wicking on the membrane, and the test reagents at the control line and the conjugate-color indicator are reactive. In addition, if the test is performed correctly and the device is working properly, the background in the Result window will become clear and provide a distinct result. This may be considered an internal negative procedural control.

The positive and negative procedural controls contained in each **AccuSign®** ***DOA 7*** test device satisfy the requirements of testing a positive control and a negative control on a daily basis. If the Control line does not appear in the Control position, the test is invalid and a new test should be performed. If the problem persists, contact PBM for technical assistance.

External Control: External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing practice. For information on how to obtain controls, contact PBM's Technical Services.

Expected Values

AccuSign® *DOA 7 THC/OPI/COC/MET/BZO/MTD/AMP* is a qualitative test. The amount of THC, opiates, cocaine, methamphetamine, benzodiazepines, methadone, amphetamine, and/or their metabolites present in the urine cannot be estimated by the test. The test results distinguish positive from negative samples. Positive results indicate the samples contain THC, opiates, cocaine, methamphetamine, benzodiazepines, methadone, amphetamine, and/or their metabolites above the cutoff concentration. The **AccuSign®** *DOA 7* test has been shown to detect following cutoff level for each drug: 50 ng/mL of THC, 300 ng/mL of morphine, 300 ng/mL of benzoylecgonine, 1000 ng/mL of methamphetamine, 300 ng/mL of oxazepam, 300 ng/mL of methadone, and 1000 ng/mL of amphetamine and in urine.

Performance Characteristics

The accuracy of **AccuSign®** *DOA 7 THC/OPI/COC/MET/BZO/MTD/AMP* test was evaluated in comparison to a commercially available immunoassay **AccuSign®** THC, **AccuSign®** OPI, **AccuSign®** COC, **AccuSign®** MET, **AccuSign®** BZO, **AccuSign®** MTD and **AccuSign®** AMP which are proven to be substantially equivalent to Syva's Emit II. The results are shown in Tables 1, 2, 3, 4, 5, 6, and 7. A complete agreement (100 %) was observed.

Table 1. THC Accuracy: Comparison of **AccuSign®** *DOA 7* with **AccuSign®** THC

		AccuSign® THC		
		Positive	Negative	Total
AccuSign® *DOA 7* (THC)	Positive	150	0	150
	Negative	0	200	200
	Total	150	200	350

Table 2. Opiates Accuracy: Comparison of **AccuSign®** *DOA 7* with **AccuSign®** OPI

		AccuSign® OPI		
		Positive	Negative	Total
AccuSign® *DOA 7* (OPI)	Positive	150	0	150
	Negative	0	200	200
	Total	150	200	350

Table 3. Cocaine Accuracy: Comparison of **AccuSign®** *DOA 7* with **AccuSign®** COC

		AccuSign® COC		
		Positive	Negative	Total
AccuSign® *DOA 7*	Positive	150	0	150
(COC)	Negative	0	200	200
	Total	150	200	350

Table 4. Methamphetamine Accuracy: Comparison of **AccuSign®** *DOA 7* with **AccuSign®** MET

		AccuSign® MET		
		Positive	Negative	Total
AccuSign® *DOA 7*	Positive	96	0	96
(MET)	Negative	0	150	150
	Total	96	150	246

Table 5. Benzodiazepine Accuracy: Comparison of **AccuSign®** *DOA 7* with **AccuSign®** BZO

		AccuSign® BZO		
		Positive	Negative	Total
AccuSign® *DOA 7*	Positive	174	0	174
(BZO)	Negative	0	200	200
	Total	174	200	374

Table 6. Methadone Accuracy: Comparison of **AccuSign®** *DOA 7* with **AccuSign®** MTD

		AccuSign® MTD		
		Positive	Negative	Total
AccuSign® *DOA 7*	Positive	100	0	100
(MTD)	Negative	0	153	153
	Total	100	153	253

Table 7. Amphetamine Accuracy: Comparison of **AccuSign®** *DOA 7* with **AccuSign®** AMP

		AccuSign® AMP		
		Positive	Negative	Total
AccuSign® *DOA 7*	Positive	98	0	98
(AMP)	Negative	0	200	200
	Total	98	200	298

In a separate study, **AccuSign®** *DOA 7 THC/OPI/COC/MET/BZO/MTD/AMP* test was evaluated against specimens confirmed as positive by GC/MS, for each of the 7 drugs. The results are shown in Table 8.

Table 8. Comparison of AccuSign® *DOA 7* **with GC/MS Assay**

	Concentration (GC/MS value) ng/mL	**Number of Samples**	**AccuSign** *DOA 7* **Result**
11-nor-Δ^9-THC-9-COOH	73 – 910	37	+
	34, 36, 37, 38, 39	5	–
Morphine	362 - 172440	31	+
	192, 215, 226, 230	4	–
Benzoylecgonine	371 – 64800	41	+
	220, 220, 224, 225, 271	5	–
Methamphetamine	1463 - 5227	15	+
	706, 750, 770, 860	4	–
Oxazepam	370 – 8641	28	+
	210, 225, 230	3	–
Methadone	307 –6523	43	+
	183, 220, 225	3	–
Amphetamine	1269 – 16000	40	+
	717, 824, 847, 866, 870, 780	6	–

Precision

The precision of the **AccuSign®** *DOA 7* test was determined by two people on five different days with serially diluted each standard drug solutions. All samples containing 50% below cutoff level of the drug showed negative results. All samples containing 50 % above cutoff level of the drug showed positive results. The study also included 20 samples of 25% below cutoff level and 20 samples of 25 % above cutoff level for each of the 7 drugs. The results are summarized below.

Table 9. Precision Study

THC Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (–)	% Agreement
25	20	0	20	100
37.5	20	0	20	100
62.5	20	19	1	95
75	20	20	0	100

Opiates Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (–)	% Agreement
150	20	0	20	100
225	20	0	20	100
375	20	20	0	100
450	20	20	0	100

Cocaine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (–)	% Agreement
150	20	0	20	100
225	20	0	20	100
375	20	20	0	100
450	20	20	0	100

Methamphetamine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (–)	% Agreement
500	20	0	20	100
750	20	0	20	100
1250	20	18	2	90
1500	20	20	0	100

Benzodiazepine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (–)	% Agreement
150	20	0	20	100
225	20	0	20	100
375	20	19	1	95
450	20	20	0	100

Methadone Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (–)	% Agreement
150	20	0	20	100
225	20	0	20	100
375	20	19	1	95
450	20	20	0	100

Amphetamine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (–)	% Agreement
500	20	0	20	100
750	20	0	20	100
1250	20	17	3	85
1500	20	20	0	100

Distribution of Random Error

Forty blind samples for each drug were prepared by spiking various concentrations of each of the 7 drugs and separately tested by two operators. The tested concentrations were 0, 50% below cutoff, 50% above cutoff and 100% above cutoff for each drug. The test results from the two operators showed complete agreement.

Reproducibility

The reproducibility of the **AccuSign®** *DOA 7* test was examined at three different sites using a total of 55 blind controls. These consisted of five negative samples, five 50% below cutoff level samples, five 100% above cutoff level samples for each of the 7 drugs. The results obtained at these three sites with these controls demonstrated 100% agreement with each other.

Specificity

The following table lists compounds that are detected by the **AccuSign®** *DOA 7* test. The specificity of the **AccuSign®** *DOA 7* test was determined by adding various drugs and drug metabolites to drug-negative urine specimens and testing with the **AccuSign®** *DOA 7* test. The results are expressed in terms of the minimum concentration required to produce a positive result (Table 10).

Table 10. Specificity

Compound	Concentration (ng/mL)
THC	
Cannabinol	10,000
11-hydroxy-Δ^9-THC	4,000
11-nor-Δ^8-THC-9-COOH	100
11-nor-Δ^9-THC-9-COOH	50
Δ^8-THC	10,000
Δ^9-THC	5,000
OPI	
Codeine	300
Hydrocodone	500
Hydromorphone	500
Lavofloxacin	100,000
Levophanol	5,000
Meperidine	>100,000
Morphine	300
Morphine-3-ß-D-glucuronide	300
Nalorphine	15,000
Naloxone	>100,000
Norcodeine	>100,000
Oxycodone	5,000
Oxymorphone	20,000
Thebaine	10,000
Tramadol	>100,000
COC	
Benzoylecgonine	300
Cocaine HCl	>100,000
Ecgonine HCl	>100,000
MET	
D-Amphetamine	>100,000
D,L-Amphetamine	>100,000
(–)Ephedrine	>100,000
(±)Ephedrine	>100,000
Isometheptene	12,500
D-Methamphetamine	1,000
p-OH-Methamphetamine	1,000
Methylenedioxyamphetamine	>100,000
Methylenedioxyethylamphetamine (MDEA)	100,000
Methylenedioxymethamphetamine	1,000
BZO	
Alprazolam	100,000
Bromazepam	1,250
Chlordiazepoxide	500
Clobazam	>100,000
Clonazepam	30,000
Clorzepate dipotassium	2,000
Delorazepam	1,500
N-Desalkylflurazepam	2,500
Diazepam	10,000
Estazolam	>100,000
Flunitrazepam	>100,000
7-amino flunitrazepam	1,500
a-Hydroxyalprazolam	100,000
a-Hydroxytriazolam	10,000
Lorazepam	2,500
Lormetazepam	25,000
Medazepam	10,000
Midazolam	25,000
Nitrazepam	100,000
Nordiazepam (N-Desmethyldiazepam)	7,500
Oxazepam	300
Prazepam	>100,000
Temazepam	6,000
Triazolam	>100,000
MTD	
Diphenhydramine	>100,000
Doxylamine	>100,000
EDDP	>100,000
EMDP	>100,000
Imipramine	>100,000
LAAM	900
Meperidine	300
Methadone	>100,000
Nor-LAAM	3,000
AMP	
D-Amphetamine	1,000
D,L-Amphetamine	1,800
L-Amphetamine	37,500
Benzphetamine	>100,000
D-Methamphetamine	>100,000
p-OH-Methamphetamine	>100,000
Methylenedioxyamphetamine	2,000
Methlyenedioxymethamphetamine	>100,000
ß-Phenethylamine	40,000
l-Phenylpropanolamine	>100,000
Phentermine	>100,000
Tryptamine	50,000
Tyramine	70,000
3-OH-Tyramine	50,000

Interfering Substances

Endogenous compounds:

The **AccuSign®** *DOA 7* test showed no interference when the endogenous compounds were added at the concentrations given below to urine samples which had ± 25 % cutoff concentration of each of the 7 drugs (Table 11).

Table 11. Endogenous Compounds

Substance Added	Concentration
Bilirubin	2 mg/dl
Creatinine	20 mg/dl
Glucose	1500 mg/dl
Hemoglobin	25 mg/dl
b-Hydroxybutyric Acid (Ketone Body)	100 mg/dl
Protein	2000 mg/dl
Sodium Chloride	1500 mg/dl
Sodium Nitrite	100 mg/dl

Exogenous compounds:

The following compounds showed no cross-reactivity when tested with the **AccuSign**® ***DOA 7*** *THC/OPI/COC/MET/BZO/MTD/AMP* at a concentration of 100 µg/mL (Table 12).

Table 12. Non Cross-Reacting Compounds

4-Acetamidophenol	Methaqualone
Acetophenetidin (Phenacetin)	Methoxyphenamine
N-Acetylprocainamide	Methylphenidate
Acetylsalicylic acid	Methyprylon
Aminopyrine	Nalidixic acid
Amoxapine	Naltrexone
Amoxicillin	Naproxen
Apomorphine	Niacinamide
Aspartame	Nifedipine
Atropine	Norethindrone
Benzilic acid	Noroxymorphone
Benzoic acid	D-Norpropoxyphene
Benzphetamine	(–) Norpseudoephedrine
Chloralhydrate	Noscapine
Chloramphenicol	Nylidrin
Chlorothiazide	D,L-Octopamine
Chlorquine	Oxalic acid
Cholesterol	Oxolinic acid
Clonidine	Oxymetazoline
Cortisone	Papaverine
(–) Cotinine	Penicillin-G
Deoxycorticosterone	Pentazocaine
Dextromethorphan	Phendimetrazine
Diclofenac	Phenelzine
Diethylpropion	Prednisolone
Diflunisal	Prednisone
Digoxin	Promethazine
Domperidone	D,L-Propanolol
Doxylamine	Propiomazine
Erythromycin	D-Propoxyphene
ß-Estradiol	Quinidine
Estrone-3-sulfate	Quinine
Ethyl-p-aminobenzoate	Rantidine
Fenoprofen	Salicylic acid
Furoxmide	Serotonin
Gentisic acid	Sulfamethazine
Glutethimide	Sulindac
Guaifenesin	Tetracycline
Hippuric acid	Tetrahydrocortisone
Hydralazine	Tetrahydrozoline
Hydrochlorothiazide	Thiamine
Hydrocortisone	Thioridazine
O-Hydroxyhippuric acid	D,L-Thyroxine
Iproniazid	Tolbutamide
(–) Isoproterenol	Triamterene
Isoxsuprine	Trifluoperazine
Ketoprofen	Trimethoprim
Labetalol	D,L-Tryptophan
Lidocaine	D,L-Tyrosine
Loperamide	Uric acid
Loxapine succinate	Verapamil
Meprobamate	Zomepirac

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Symbols Key

	Manufactured by
CE	CE Mark
EC REP	Authorized Representative
IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog Number
	Consult Instructions for Use
LOT	Batch Code
EXP YYYY-MM-DD	"Use By" date in year-month-day format
2°C (35°F) Min / 30°C (86°F) Max	Temperature Limitation
Σ n	Contains sufficient for <n> tests
	Do not reuse
CONT	Contents
DEV	Test Device
PIP	Transfer Pipette
IFU	Instructions for Use
TEST DRUG	One-step immunochromatographic Assay for the Detection of Drugs of Abuse in Urine

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