

The following compounds show no cross-reactivity when tested with **AccuSign® THC** at a concentration of 100 µg/mL (Table 4).

Table 4. Non Cross-Reacting Compounds

4-Acetamidophenol	Ecgonine methyl-ester	(±) 3,4-Methylene-dioxymethamphetamine
Acetophenetidin (Phenacetin)	(+) Ephedrine	Methylphenidate
N-Acetylprocainamide	(±) Ephedrine	Methyprylon
Acetylsalicylic acid	(-) Ephedrine	Morphine-3-β-D-glucuronide
Aminopyrine	(-) Ψ Ephedrine	Nalidixic acid
Amitriptyline	Erythromycin	Nalorphine
Amobarbital	β-Estradiol	Naloxone
Amoxapine	Estrone-3-sulfate	Naltrexone
Amoxicillin	Ethyl-p-amino-benzoate	Naproxen
D,L-Amphetamine	Fenopropfen	Niacinamide
l-Amphetamine	Furoxime	Nifedipine
Apomorphine	Gentisic acid	Norcodein
Aspartame	Glucuronide	Norethindrone
Atropine	Glutethimide	Noroxymorphone
Benzilic acid	Guaifenesin	D-Norpropoxyphene
Benzoic acid	Hippuric acid	(-) Norpseudoephedrine
Benzoylcegonine	Hydralazine	Noscapine
Benzphetamine	Hydrochlorothiazide	Nylidrin
Butabarbital	Hydrocodone	D,L-Octopamine
Cannabidiol	Hydrocortisone	Oxalic acid
Chloralhydrate	Hydromorphone	Oxazepam
Chloramphenicol	O-Hydroxyhippuric acid	Oxolinic acid
Chlordiazepoxide	3-Hydroxytyramine	Oxycodone
Chlorothiazide	Ibuprofen	Oxymetazoline
Chlorpromazine	Imipramine	Oxymorphone
Chlorquine	Iproniazid	Papaverine
Cholesterol	(-) Isoproterenol	Penicillin-G
Clomipramine	Isoxsuprine	Pentazocaine
Clonidine	Ketamine	Pentobarbital
Cocaine hydrochloride	Ketoprofen	Perphenazine
Codeine	Labetalol	Phencyclidine
Cortisone	Levorphanol	Phendimetrazine
(-) Cotinine	Lidocaine	Phenelzine
Creatinine	Loperamide	Phenobarbital
Deoxycorticosterone	Loxapine succinate	Phentermine
Dextromethorphan	Maprotiline	Phentoin
Diazepam	Meperidine	L-Phenylephrine
Diclofenac	Meprobamate	β-Phenylethylamine
Diethylpropion	Methadone	Phenylpropanolamine
Diflunisal	p-Hydroxymethamphetamine	Prednisolone
Digoxin	Methaqualone	Prednisone
Diphenhydramine	Methoxyphenamine	Procaine
Domperidone	(±) 3,4-Methylene-dioxyamphetamine	Promazine
Doxylamine		Promethazine
Ecgonine hydrochloride		

D,L-Propranolol	Sulfamethazine	Triamterene
Propiomazine	Sulindac	Trifluoperazine
D-Propoxyphene	Temazepam	Trimethoprim
D-Pseudoephedrine	Tetracycline	Trimipramine
Quinidine	Tetrahydrocortisone	Tryptamine
Quinine	Tetrahydrozoline	D,L-Tryptophan
Rantidine	Thebaine	Tyramine
Salicylic acid	Thiamine	D,L-Tyrosine
Secobarbital	Thioridazine	Uric acid
Serotonin	D,L-Thyroxine	Verapamil
	Tolbutamide	Zomepirac

References

- Hawks RL, Chiang CN, eds. *Urine Testing for Drugs of Abuse*, Rockville, MD: National Institute for Drug Abuse (NIDA), Research Monograph 73; 1986.
- Tietz, Norbert W. *Textbook of Clinical Chemistry*. W.B. Saunders Company. 1986.

Symbols Key

	Manufactured by
	CE Mark
	Authorized Representative
	In Vitro Diagnostic Medical Device
	Catalog Number
	Consult Instructions for Use
	Batch Code
	“Use By” date in year-month-day format
	Temperature Limitation
	Contains sufficient for <n> tests
	Do not reuse
	Contents
	Test Device
	Transfer Pipette
	Instructions for Use
	One-step immunochromatographic Assay for the Detection of Drugs of Abuse in Urine
	Marijuana Test

P-5836-G

AccuSign® THC

One-Step THC Test

For *In Vitro* Use Only

Simple One-Step Immunoassay for the Qualitative Detection of THC Metabolites in Urine

PBM

Catalog No.	DOA-201-35	35 Test Kit
	DOA-201-10	10 Test Kit

Intended Use

AccuSign® THC is a simple, one-step immunochromatographic assay for the rapid, qualitative detection of THC metabolites in urine. The test is intended for use in the qualitative detection of cannabinoids in human urine with a cutoff at 50 ng/mL for 11-nor-Δ⁹-THC-9-COOH.

*The AccuSign® THC 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 (Δ⁹-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When ingested or smoked, it produces euphoric effects. Users have impairment of short term memory and THC use slows learning. Also, it may cause transient episodes of confusion, anxiety, or even 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-Δ⁹-tetrahydrocannabinol-9-carboxylic acid.²

Principle

The **AccuSign® THC** 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 for binding to the antibodies between drug conjugates and drugs which may be present in the urine sample. In the test procedure, a sample of urine is placed in the sample well of the device, and the sample is allowed to migrate upward. If drug is present in the urine sample, it competes with the drug conjugate, which is immobilized on the membrane, for the limited antibodies present in the form of dye-antibody conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the dye-antibody conjugate cannot bind to the drug conjugate on the membrane. Therefore, a drug-positive urine sample will not generate a line at the Test position in the Result Window, indicating a positive result from positive drug competition, while a negative urine sample will generate a line at the Test position in the Result Window, indicating a negative result from an absence of competition with free drug.

In addition, the test card has a procedural control built into the system, at the Control position in the Result Window. The control line is immobilized with polyclonal anti-mouse antibody; therefore, it will capture monoclonal antibody-dye conjugates that pass the region, showing a colored line at the Control (validation) position. The line works as a procedural control, confirming that proper sample volume was used and the reagent system worked. If insufficient sample volume is used, there may not be a control line, indicating the test is invalid.

Materials Provided

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

- AccuSign® THC** device. The test device contains a membrane strip coated with drug conjugate and a dye pad containing anti-THC antibody-dye conjugate in a protein matrix.
- 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 established according to good laboratory practices.
- The **AccuSign®** device should remain in its original sealed pouch until ready for use. Do not use the test if the pouch is damaged or the seal is broken.
- Do not use the test kit after the expiration date.

Storage and Stability

The **AccuSign® THC** test kit should be stored at 2–30°C (36–86°F) in the original sealed pouch. The expiration dating given was established under these storage conditions.

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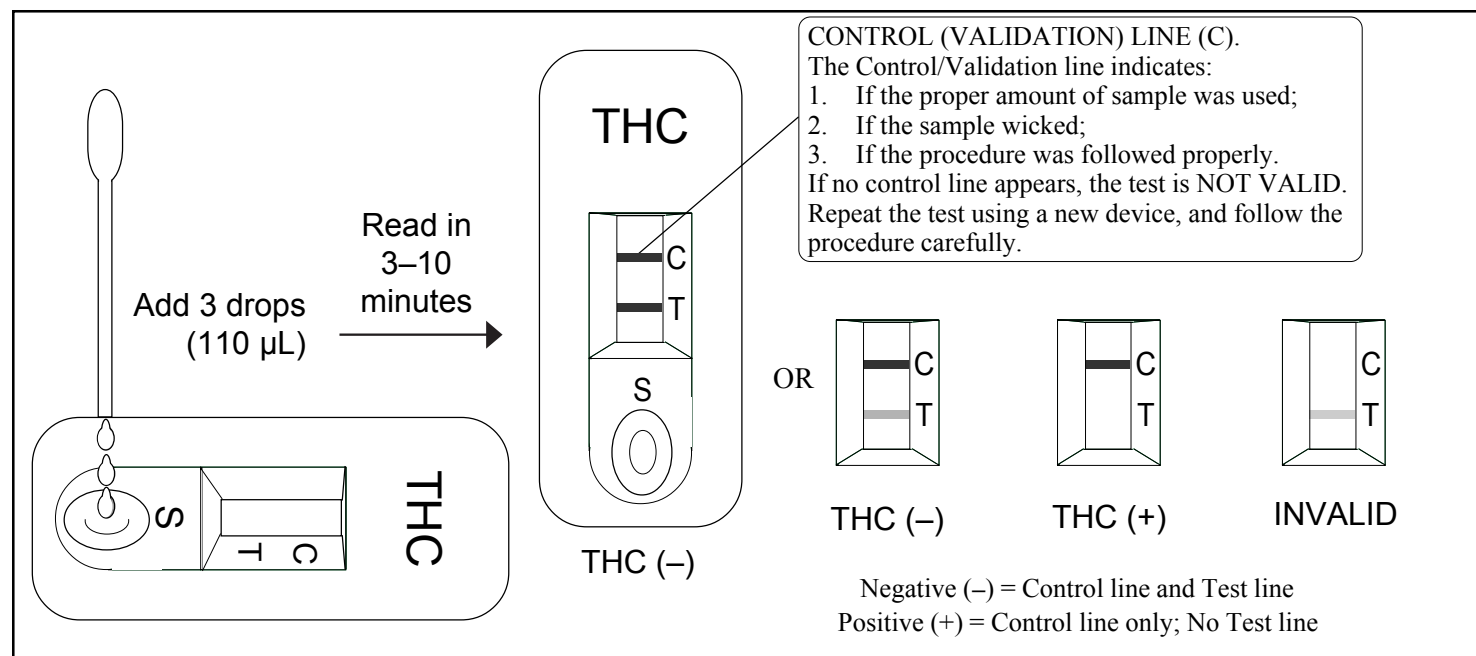
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Specimen Collection and Preparation

Approximately 110 µL of urine sample is required for each test. 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. Specimens should be brought to room temperature before testing.

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 the Sample well of the device and watching for the appearance of colored lines in the result window.

Test Protocol

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

Interpretation of Results

Negative: The appearance of a reddish-purple Control line (C) and a line next to T indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and the Test line may not be equal. *Any faint Test line 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 only a reddish-purple Control line and no distinct line next to T indicates the test result is positive for THC (i.e., the specimen contains THC 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® THC** test device.

Limitations

- The test is designed for use with unadulterated human urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine sample which are not listed in Table 4 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 must be read within 10 minutes of sample application.
- Prolonged passive smoking of THC may produce a positive result.

User Quality Control

Internal Control: Each **AccuSign® THC** test device has a built-in control. The Control line is an internal positive proce-

dural control. A distinct reddish-purple Control line should appear at the Control position in the Result Window, 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® THC** 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 at the Control position in the Result Window, 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® THC is a qualitative assay. The amount of THC metabolites present in the urine cannot be estimated by the assay. The assay results distinguish positive from negative samples. Positive results indicate the samples contain cannabinoids above the cutoff concentration.

Performance Characteristics

The National Institute on Drug Abuse has suggested that the screening cutoff for positive samples be 50 ng/mL for THC. The **AccuSign® THC** test has been shown to detect THC metabolite, 11-nor- Δ^9 -THC-9-COOH, in urine at the cutoff of 50 ng/mL.

The accuracy of **AccuSign® THC** was evaluated in comparison to a commercially available immunoassay (Syva® EMIT® II). A total of 1000 samples was tested by both procedures. The results are shown below (Table 1).

Table 1. Accuracy: Comparison of AccuSign® THC with Syva® EMIT® II

	Syva® EMIT® II (THC)			
	Positive	Negative	TOTAL	
AccuSign® THC	Positive	327	5	332
	Negative	13	655	668
TOTAL		340	660	1000
	Relative Sensitivity	Relative Specificity		
THC	96.2% (327/340)	99.2% (655/660)		

In a separate study, **AccuSign® THC** was evaluated against specimens confirmed as positive by GC/MS. The results below demonstrate the excellent correlation of **AccuSign® THC** with GC/MS (99% agreement, Table 2).

Table 2. Accuracy: Comparison of AccuSign® THC with GC/MS Assay

		AccuSign® THC	GC/MS
THC	Positive	87	88
	Negative	1	0

Precision and Accuracy

The precision of the **AccuSign® THC** assay was determined by carrying out the test with serially diluted standard drug solutions. Ninety-five percent of the samples containing 50% over the cutoff level of the drug consistently showed positive results.

The study also included over 40 samples containing $\pm 25\%$ of cutoff level. These results were found to be consistently in agreement with predicate test results.

Distribution of Random Error:

Twenty blind samples prepared by spiking various concentrations of THC were separately tested by two operators. The test results from the two operators showed complete agreement.

Reproducibility

The reproducibility of the test results of the **AccuSign® THC** test was examined at three different sites using a total of 15 blind controls, consisting of 5 negative samples, 5 moderately positive samples (i.e., a concentration 1.5 times the cutoff level), and 5 strongly positive samples (i.e., a concentration 3 times the cutoff level). 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® THC** test. The specificity of the **AccuSign® THC** test was determined by adding various drugs and drug metabolites to drug-negative urine specimens and testing with the **AccuSign® THC** test kit. The results are expressed in terms of the concentration required to produce a positive result (Table 3).

Table 3. Specificity

Compound	Concentration (ng/mL)
Cannabinol	>100,000
11-hydroxy- Δ^9 -THC	7,500
11-nor- Δ^8 -THC-9-COOH	250
11-nor- Δ^9 -THC-9-COOH	50
Δ^8 -THC	>100,000
Δ^9 -THC	>100,000