References

1. Tietz, Norbert W. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986, p. 1735.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73; 1986.
3. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed., Davis, CA: Biomedical Publ.; 1982; p.488.
4. Ambre J. J. Anal. Toxicol. 1985;9:241–5.
5. Blum K. Handbook of Abusable Drugs. 1st ed. New York: Gardner Press, Inc.; 1984.

Symbols Key

	Instructions For Use (Read)		Transfer Pipette
REF	Item Number	IVD	For In Vitro Diagnostic Use
	Store At	LOT	Lot Number
	Expiration Date		Manufacturer
CONT	Contents		Manufactured For
IFU	Instructions For Use	EC REP	Authorized Representative
		CE	CE Mark

Printed in U.S.A.
P-S8241-E
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CE

EC REP

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P-S8241-E

Status DS STIK

THC/OPI/COC/AMP or MET
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,
Amphetamine or Methamphetamine and/or their
Metabolites in Urine

LifeSign, LLC

Item No.	14035	THC/OPI/COC/AMP	35 Test Kit
Item No.	14010	THC/OPI/COC/AMP	10 Test Kit
Item No.	14135	THC/OPI/COC/MET	35 Test Kit
Item No.	14110	THC/OPI/COC/MET	10 Test Kit

Intended Use

The Status DS Stik THC/OPI/COC/AMP OR MET Panel Assay is a simple, one-step immunochromatographic test for the rapid, qualitative detection of THC, opiates, cocaine, amphetamine or methamphetamine and/or their metabolites in human urine. The test detects the major metabolites of these drugs at the following cutoff concentrations.

THC	11-nor-Δ⁹-THC-9-carboxylic acid	50 ng/mL
OPI	Morphine	300 ng/mL
COC	Benzoylecgonine	300 ng/mL
AMP	D-Amphetamine	1000 ng/mL
MET	D-Methamphetamine	1000 ng/mL

The Status DS Stik THC/OPI/COC/AMP OR MET 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 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-Δ⁹-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.[1,2,3]

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.[2,4]

Amphetamine 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.[5] Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses include anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of amphetamine generally last 2–4 hours, and the drug has a half-life of 9–24 hours in the body. Amphetamine is excreted in the urine in unchanged form and also as hydroxylated and deaminated derivatives.[1,5]

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.[5] However, 10–20% of methamphetamine is excreted as the unchanged compound. 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.

Principle

The Status DS Stik (THC/OPI/COC/AMP or MET) test uses solid-phase chromatographic membrane immunoassay technology for the qualitative, simultaneous detection of THC, opiates, cocaine, and amphetamine or methamphetamine 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 from positive drug competition. A negative urine sample will generate a line at the specific drug position in the Result window, indicating a negative result from an absence of competition with free drugs. 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 Status DS Stik test kit contains all the reagents necessary to perform the assay.

- Status DS Stik device. The test device contains a membrane strip and a dye pad. The membrane strip is coated with THC-protein (from a purified bovine protein source) conjugate, -protein (from a purified bovine protein source) conjugate, monoclonal anti-amphetamine or anti-methamphetamine, anti-morphine, and anti-benzoylecgonine antibodies.

  Sheep antimouse IgG antibody is coated for the control band. The dye pad contains colloidal gold coated with monoclonal anti-THC, anti-phencyclidine antibodies, as well as conjugates of methamphetamine or amphetamine, morphine, and benzoylecgonine (each drug is conjugated with purified bovine source protein).

- Instructions for use.

Precautions

- For in vitro diagnostic use only.
- Avoid cross contamination of urine samples by using a new urine specimen container.
- 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 Status DS Stik device should remain in its original sealed pouch until ready for use.
- Do not use the test if the pouch is damaged and the seal is broken. The test kit can be damaged by moisture in the air.
- Do not use the test kit after the expiration date.

Storage and Stability

The Status DS Stik 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

Collect sufficient urine sample to completely cover the Status DS Stik 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 within 2 hours, specimens should be refrigerated (2–8°C) for up to 48 hours. If longer storage is required, specimen may be stored frozen (-20°C or colder).

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

Test Procedure

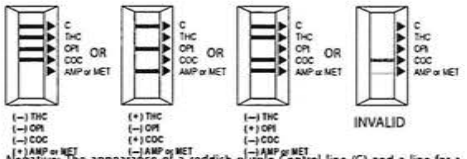
Test Protocol

1. For each test, open one Status DS Stik pouch and label the Status DS Stik device with the patient ID.

2. Remove cap and immerse the Sample well end of the Status DS Stik so that the sample covers the Sample well and hold until specimen starts migrating through Result window (approximately 7 seconds). Do not immerse above the maximum dipping line or allow sample to touch the Result window.

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. Note: The Control line and specific drug lines may not be of the same intensities. Any faint line next to a specific drug name, 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 line next to 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 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 Status DS Stik test device.Examples of possible results are shown in the diagram above.

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 substances in the urine sample other than those listed in Table 2, 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.
- Some drugs or their metabolites are known to stick to certain plastics. Therefore, the drug concentration may be reduced while transferring the urine to different containers, or storing it over a prolonged period, thus producing different results when tested at different times.
- 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.
- Status DS Stik device should be opened immediately before use. If left opened for long periods of time before used, device may not perform properly.

User Quality Control

Internal Control: Each Status DS Stik 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 Status DS Stik 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 LifeSign 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 LifeSign's Technical Services.

Expected Values

Status DS Stik is a qualitative assay. The amount of drugs and metabolites present in urine cannot be estimated by the assay. The assay results distingulsh positive from negative samples. Positive results indicate the samples contain the specific drug above the cutoff concentration.

Performance Characteristics

The accuracy of the Status DS Stik (THC/OPI/COC/AMP or MET) test was evaluated in comparison with a commercially available immunoassay, AccuSign®DOA4 (THC/OPI/COC/AMP or MET). A complete agreement (100%) was observed between two tests (Table 1).

Table 1. Accuracy: Comparison of Status DS Stik with AccuSign® DOA4

		Status DS Stik	AccuSign® DOA4
THC	Positive	40	40
	Negative	40	40
OPI	Positive	40	40
	Negative	40	40
COC	Positive	34	34
	Negative	46	46
AMP	Positive	37	37
	Negative	43	43
MET	Positive	38	38
	Negative	42	42

Precision

The precision of the Status DS Stik was determined by two people performing the test on three different days with serially diluted standard solutions of six drugs. 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 six drugs. The results of the test using samples containing ±25% of the cutoff level were found to be consistently in agreement with expected test results.

Distribution of Random Error

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

Reproducibility

The reproducibility of the test results of the Status DS Stik test was examined at three different sites using a total of 65 blind controls. These consisted of five negative samples, five 50% below cutoff level samples, five 100% above cutoff level samples for each of the six drugs. The results obtained in these three sites with these controls demonstrated 100% agreement with each other.

Specificity and Cross Reactivity

The following table lists compounds that are detected by the Status DS Stik THC/OPI/COC/AMP OR MET test. The specificity of the Status DS Stik test was determined by adding various drugs or drug metabolites to drug negative urine specimens and testing with the Status DS Stik test. The results are expressed in terms of the minimum concentration required to produce a positive result (Table 2).

Table 2. Specificity

Compound	Concentration (ng/mL)
THC	
~~Cannabinol~~	~~>100,000~~
11-nor-Δ⁹-THC-9-COOH	250
11-nor-Δ⁸-THC-9-COOH	50
Δ⁹-THC	>100,000
Δ⁸-THC	>100,000
11-hydroxy-Δ⁹-THC	7,500
OPI	
Codeine	300
Hydrocodone	500
Hydromorphone	600
Levophanol	5,000
Meperidine	80,000
Morphine 300	
Morphine-3-ß-D-glucuronide	500
Nalorphine	1,000
Naloxane 100,000	
Norcodeine	60,000
Oxycodone	20,000
Oxymorphone	60,000
Procaine HCl	100,000
Thebaine	5,000
COC	
Benzoylecgonine	300
Cocaine HCl	300
Ecgonine HCl	>100,000
AMP	
D-Amphetamine	1,000
D,L-Amphetamine	1,500
L-Amphetamine	60,000
Methylenedioxyamphetamine	700
ß-Phenethylamine	60,000
Phentermine	350
Tryptamine	50,000
Tyramine	70,000
MET	
D-Amphetamine	200,000
D,L-Amphetamine	>200,000
(–)Ephedrine	200,000
(+)Ephedrine	200,000
D-Methamphetamine	1,000
p-OH-Methamphetamine	>200,000
Methylenedioxyamphetamine	>200,000
Methylenedioxymethamphetamine	2,000

The following compounds showed no cross-reactivity when tested with the Status DS Stik (THC/OPI/COC/AMP or MET) at a concentration of 100 µg/mL (Table 3).

Table 3. Non Cross-Reacting Compounds

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