Cyclopentobarbital	400
Pentobarbital	2,000
Phenobarbital	5,000
Penytoin	4,000
Secobarbital	300
Thiopental	>100,000
MTD	
Diphenhydramine	>100,000
Doxylamine	>100,000
EDDP	>100,000
EMDP	>100,000
Imipramine	>100,000
LAAM	900
Methadone	300
Meperidine	>100,000
Nor-LAAM	3,000
TCA	
Amitryptiline	800
Chlorpromazine	100,000
Clomipramine	5,000
Cyclobenzaprine	2,500
Desipramine	1,500
Diphenhydramine	>100,000
Dothiepin	2,000
Doxepin	1,500
Imipramine	1,000
Norclomipramine	850
Nordoxepin	5,000
Nortriptyline	1,000
Perphenazine	41,000
Promazine	5,000
Protryptiline	2,000
Trimipramine	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-Phenylethylamine	40,000
I-Phenylpropanolamine	>100,000
Phentermine	>100,000
Tryptamine	50,000
Tyramine	70,000
3-OH-Tyramine	50,000

Interfering Substances

Endogenous compounds:
The ***Status DS*** 10 PANEL (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) 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 10 drugs.

Table 15. 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 ***Status DS*** 10 PANEL (MET/OPI/COC/THC/PCP/BZO/BAR /MTD/TCA/AMP) at a concentration of 100 µg/mL. (Table 16.)

Table 16. Non Cross-Reacting Compounds

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

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Symbols Key

	Instructions For Use (Read)	PIP	Transfer Pipette
REF	Item Number	IVD	For In Vitro Diagnostic Use
2°C 30°C	Store At	LOT	Lot Number
	Expiration Date		Manufacturer
CONT	Contents	MF	Manufactured For
IFU	Instructions For Use	EC REP	Authorized Representative
		CE	CE Mark

Printed in U.S.A.
P-58196-F
20-9/6/19

CE

EC REP

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Manufactured by PBM

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MF Manufactured for: lifeSign

A PBM Group Company
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Skillman, NJ 08558
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www.lifesignmed.com

P- 58196-F

Status DS

MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP
One-Step Panel Test for Drugs of Abuse

For *In Vitro* Use Only

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

LifeSign, LLC

Item No. 21010 10 Test Kit

Item No. 21025 25 Test Kit

Intended Use

Status DS 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) test is a simple, one-step immunochromatographic assay for the rapid, qualitative detection of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants, amphetamine, and/or their metabolites present in human urine at the cutoff concentration of the drug specified (see Expected Values).

Status DS **10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD /TCA/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.[2]**

Summary and Explanation

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.[3] 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.

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 of 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.[3,5]

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.[1]

Phencyclidine is an arylcyclohexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, angel dust, love boat, hog, or killer weed. PCP can produce lethargy, euphoria, ataxia, nystagmus and coma. Currently a number of PCP analogues with similar pharmacological effects are in use as street drugs, including PCE, PHP, TCP, and ketamine. Phencyclidine is readily absorbed when smoked or ingested, or even through skin contact. It is metabolized in the liver. Evidence indicates that PCP undergoes oxidative metabolism to at least 2 inactive metabolites, 4-phenyl-4-piperidino-cyclohexanol and 1-(1-phenylcyclohexyl)-4-hydroxypiperidine, which are excreted as glucuronide conjugates in the urine. About 10% of the dose is excreted in urine as the parent compound, phencyclidine.[2,3]

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]

Barbiturates are a group of chemicals derived from barbituric acid. Classified as hypnotics, they depress the central nervous system. Taken orally in pill or tablet form, they are prescribed for many medical conditions, usually for their sedative effect. Abuse of barbiturates can, however, lead not only to impaired motor coordination and mental disorder, but also to respiratory collapse, coma and death. The combination of barbiturates and alcohol is particularly dangerous. Symptoms of barbiturate abuse include drowsiness, slurred speech and irritability. Acute conditions include respiratory collapse and loss of consciousness. Chronic conditions include addiction, abstinence and seizures. The effects of short-acting barbiturates such as pentobarbital and

secobarbital last 3 to 6 hours. The effects of long-acting barbiturates last 10 to 20 hours. Phenobarbital is an example of long-acting ones. Barbiturates normally remain detectable in urine for 4 to 6 days in the case of short-acting ones and up to 30 days for long-acting ones. Short-acting barbiturates are generally excreted as metabolites, while long-acting ones primarily appear unchanged.[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]

Tricyclic antidepressants (TCAs) are a type of prescription drug intended for clinically depressed patients. Unfortunately, they are becoming more frequently abused and are now one of the leading causes of death by drug overdose in the United States. There are two broad chemical classes of TCAs. The tertiary amines—amitriptyline, imipramine, trimipramine and doxepin—boost serotonin levels and are prescribed for insomnia, irritability and over stimulation. The secondary amines—nortriptyline, desipramine and protryptiline—enhance norepinephrine levels and are prescribed for opposite types of symptoms, such as excessive fatigue, withdrawal and inertness.[1] Abuse of TCAs may lead to coma, respiratory depression, convulsions, blood pressure deviations, hyperprexia and severe cardiac conditions. TCAs are excreted in urine mostly in the form of metabolites for up to ten days.[3,7,8]

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.[3,6]

Principle

The ***Status DS*** 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR /MTD/TCA/AMP) test uses solid-phase chromatographic membrane immunoassay technology for the qualitative, simultaneous detection of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants, 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 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*** 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR /MTD/TCA/AMP) test kit contains all the reagents necessary to perform the assay.

- ***Status DS*** 10 Panel (MET/OPI/COC/THC/PCP/BZO/ BAR/MTD/TCA/AMP) device. The test device contains membrane strips and dye pads: Membrane strips are coated with THC-protein (a purified bovine protein) conjugate, PCP-protein (a purified bovine protein) conjugate, monoclonal anti-methamphetamine, anti-morphine, anti-benzoylecgonine, anti-barbiturate, and anti-amphetamine antibodies, as well as polyclonal anti-oxazepam, anti-methadone, and anti-tricyclic antidepressant antibodies. Sheep anti-mouse antibody is coated for the control band. Dye pads contain colloidal gold coated with monoclonal anti-THC, anti-phencyclidine, and mouse IgG antibodies as well as conjugates of methamphetamine, morphine, benzoylecgonine, oxazepam, barbiturate, methadone, nortriptyline analogue 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 a dropper for each urine sample.
- The 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*** 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 ***Status DS*** 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/ MTD/TCA/AMP) 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.

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

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

Tricyclic Antidepressant Test				
Drug Conc.	Number	Positive	Negative	Agreement
(ng/mL)	of Tested	(+)	(-)	%
500	20	0	20	100
750	20	0	20	100
1250	20	20	0	100
1500	20	20	0	100

Amphetamine Test				
Drug Conc.	Number	Positive	Negative	Agreement
(ng/mL)	of Tested	(+)	(-)	%
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 10 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 ***Status DS*** 10 PANEL (MET/OPI/COC /THC/PCP/ BZO/BAR/MTD/TCA/AMP) 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 10 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 ***Status DS*** 10 PANEL (MET/OPI/COC/THC/PCP/BZO/ BAR/MTD/TCA/AMP) test. The specificity of the ***Status DS*** 10 PANEL (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) test was determined by adding various drugs and drug metabolites to drug-negative urine specimens and testing with the ***Status DS*** 10 PANEL (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) test. The results are expressed in terms of the minimum concentration required to produce a positive result (Table 14).

Table 14. Specificity

Compound	**Concentration (ng/mL)**
MET	
D-Amphetamine	>100,000
D,L-Amphetamine	>100,000
(–)Ephedrine	>100,000
(+)Ephedrine	>100,000
Isometheptene	12500
D-Methamphetamine	1,000
p-OH-Methamphetamine	3,000
Methylenedioxyamphetamine	>100,000
Methylenedioxyethylamphetamine(MDEA)	100,000
Methylenedioxymethamphetamine	1,000
OPI	
Codeine	300
Hydrocodone	500
Hydromorphone	500
Lavofloxacin	100,000
Levophanol	5000
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
THC	
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
PCP	
Phencyclidine	25
Thienylcyclohexyl-piperidine	450
BZO	
Alprazolam	100,000
Bromazepam	1,250
Chlordiazepoxide	500
Clobazam	>100,000
Clonazepam	30,000
Clorazepate dipotassium	2000
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
BAR	
Allobarbital	400
Alphenal	250
Amobarbital	5,000
Aprobarbital	400
Barbital	1,500
Butalbital	800

Benzodiazepine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
150	25	0	25
225	25	0	25
300	25	0	25
375	25	22	3
450	25	25	0
600	25	25	0

Barbiturate Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
150	25	0	25
225	25	0	25
300	25	0	25
375	25	22	3
450	25	25	0
600	25	25	0

Methadone Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
150	25	0	25
225	25	0	25
300	25	0	25
375	25	24	1
450	25	25	0
600	25	25	0

Tricyclic Antidepressant Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
500	25	0	25
750	25	0	25
1000	25	0	25
1250	25	24	1
1500	25	25	0
2000	25	25	0

Amphetamine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
500	25	0	25
750	25	0	25
1000	25	0	25
1250	25	20	5
1500	25	25	0
2000	25	25	0

Precision

The precision of the ***Status DS*** 10 PANEL (MET/OPI/COC/THC /PCP/BZO/BAR/MTD/TCA/AMP) test was determined by two people on five different days with serially diluted standard solutions for each drug. 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 10 drugs. The results are summarized below.

Table 13. Precision Study

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

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

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

Phencyclidine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)	Agreement %
12.5	20	0	20	100
18.8	20	0	20	100
31.3	20	18	2	90
37.5	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

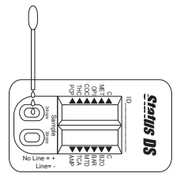
Test Procedure

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

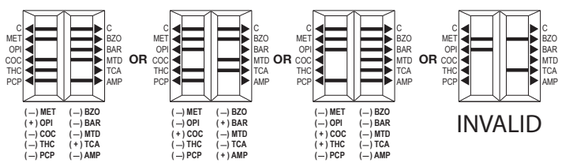
1. For each test, open one ***Status DS*** 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) pouch and label the ***Status DS*** device with the patient ID.

2. Holding the dropper vertically, dispense 3 drops (110 µL) of the urine sample into the each Sample well (S).



3. Read the result after 5 minutes, but within 10 minutes of sample addition.

Interpretation of Results



Negative: The appearance of a reddish-purple Control line (C) and a line at a specific drug position indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and specific drug line may not be equal. 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 distinct 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 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 ***Status DS*** 10 Panel test device. Examples of possible results are shown in the diagram above.

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 which are not listed in Tables 14 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. Extremely acidic (below pH 3.5) or basic (over pH 11) urine specimens may produce erroneous results.
- This test detects only the presence of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants, amphetamine and/or their metabolites in urine. A positive test result does not provide any indication of the level of intoxication or urinary concentration.
- 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.

User Quality Control

Internal Control: Each ***Status DS*** 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*** 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 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/ TCA/ AMP) is a qualitative test. The amount of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants , 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 methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants , amphetamine, and/or their metabolites above the cutoff concentration.

The ***Status DS*** 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) test has been shown to detect each drug with the following cutoff: 1000 ng/mL of methamphetamine, 300 ng/mL of morphine, 300 ng/mL of benzoylecgonine, 50 ng/mL of THC, 25 ng/mL of phencyclidine, 300 ng/mL of oxazepam, 300 ng/mL of secobarbital, 300 ng/mL of methadone, 1000 ng/mL of nortriptyline and 1000 ng/mL of amphetamine in urine.

Performance Characteristics

The accuracy of ***Status DS*** 10 Panel (MET/OPI/COC/THC/PCP/BZO /BAR/MTD/TCA/AMP) test was evaluated in comparison to a commercially available immunoassay ***Status DS*** MET, ***Status DS*** OPI, ***Status DS*** COC, ***Status DS*** THC, ***Status DS*** PCP, ***Status DS*** BZO, ***Status DS*** BAR, ***Status DS*** MTD, ***Status DS*** TCA and ***Status DS*** AMP which are proven to be substantially equivalent to Syva's Emit II, Triage® Plus TCA, and AbuScreen ONLINE™ PCP. The results are shown in Tables 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10. A complete agreement (100 %) was observed.

Table 1. Methamphetamine Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** MET

		Status DS (MET)		
		Positive	Negative	Total
Status DS 10 Panel (MET)	Positive	96	0	96
	Negative	0	150	150
	Total	96	150	246

Table 2. Opiates Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** OPI

		Status DS (OPI)		
		Positive	Negative	Total
Status DS 10 Panel (OPI)	Positive	150	0	150
	Negative	0	200	200
	Total	150	200	350

Table 3. Cocaine Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** COC

		Status DS (COC)		
		Positive	Negative	Total
Status DS 10 Panel (COC)	Positive	150	0	150
	Negative	0	200	200
	Total	150	200	350

Table 4. THC Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** THC

		Status DS (THC)		
		Positive	Negative	Total
Status DS 10 Panel (THC)	Positive	150	0	150
	Negative	0	200	200
	Total	150	200	350

Table 5. Phencyclidine Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** PCP

		Status DS (PCP)		
		Positive	Negative	Total
Status DS 10 Panel (PCP)	Positive	55	0	55
	Negative	0	153	153
	Total	55	153	208

Table 6. Benzodiazepine Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** BZO

		Status DS (BZO)		
		Positive	Negative	Total
Status DS 10 Panel (BZO)	Positive	174	0	174
	Negative	0	200	200
	Total	174	200	374

Table 7. Barbiturate Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** BAR

		Status DS (BAR)		
		Positive	Negative	Total
Status DS 10 Panel (BAR)	Positive	99	0	99
	Negative	0	204	204
	Total	99	204	303

Table 8. Methadone Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** MTD

		Status DS (MTD)		
		Positive	Negative	Total
Status DS 10 Panel (MTD)	Positive	100	0	100
	Negative	0	153	153
	Total	100	153	253

Table 9. Tricyclic Antidepressant Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** TCA

		Status DS (TCA)		
		Positive	Negative	Total
Status DS 10 Panel (TCA)	Positive	103	0	103
	Negative	0	207	207
	Total	103	207	310

Table 10. Amphetamine Accuracy: Comparison of ***Status DS*** 10 Panel with ***Status DS*** AMP

		Status DS (AMP)		
		Positive	Negative	Total
Status DS 10 Panel (AMP)	Positive	98	0	98
	Negative	0	200	200
	Total	98	200	298

In a separate study, ***Status DS*** 10 Panel (MET/OPI/COC/THC/ PCP/BZO/BAR/MTD/TCA/AMP) test was evaluated against specimens confirmed as positive by GC/MS, for each of the 10 drugs. The results are shown in Table 11.

Table 11. Comparison of ***Status DS*** 10 Panel with GC/MS Assay

	Concentration (GC/MS value) ng/mL	**Number of Samples**	**Status DS 10 Panel Result**
Methamphetamine	14630-05227 706, 750, 770, 860	15 4	15 4
Morphine	36 - 172440 192, 215, 226, 230	31 4	31 4
Benzoylecgonine	371 - 64800 220, 220, 224, 225, 271	41 5	41 5
Δ^9-THC-9-COOH	73 - 910 34, 36, 37, 38, 39	37 5	37 5
PCP	40 - 97 17, 18, 18	21 3	21 3
Oxazepam	370 - 8641 210, 225, 230	28 3	28 3
Secobarbita	324 - 14560 200, 225, 230	23 3	23 3
Methadone	307 - 6523 183, 220, 225	43 3	43 3
TCA - Nortriptyline Amitriptyline Amphetamine	1119 - 11140 700, 750, 852, 870 1269 - 16000 717, 824, 847, 866, 870, 780	19 4 40 6	19 4 40 6

Sensitivity

For each drug test the cutoff value was validated by testing spiked urine controls with concentrations of 0, 50% below cutoff, 25% below cutoff, 25% above cutoff, 50% above cutoff and 100 % above cutoff. The results of the sensitivity studies are summarized below.

Table 12. Validation of cut-off level for ***Status DS*** 10 PANEL

Drug Standards and Cutoff Values for Each Drug Test

Test Name	**Drug Standard**	**Cutoff Conc.(ng/mL)**
Methamphetamine	D-methamphetamine	1000
Opiates	Morphine	300
Cocaine	Benzoylecgonine	300
THC	11-nor-Δ^9-THC-9-COOH	50
Phencyclidine	Phencyclidine	25
Benzodiazepine	Oxazepam	300
Barbiturate	Secobarbital	300
Methadone	Methadone	300
Tricyclic Antidepressant	Nortriptyline	1000
Amphetamine	D-Amphetamine	1000

Methamphetamine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
500	25	0	25
750	25	0	25
1000	25	0	25
1250	25	20	5
1500	25	25	0
2000	25	25	0

Opiates Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
150	25	0	25
225	25	0	25
300	25	0	25
375	25	24	1
450	25	25	0
600	25	25	0

Cocaine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
150	25	0	25
225	25	0	25
300	25	0	25
375	25	22	3
450	25	25	0
600	25	25	0

THC Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
25	25	0	25
37.5	25	0	25
50	25	0	25
62.5	25	22	3
75	25	25	0
100	25	25	0

Phencyclidine Test

Drug Conc. (ng/mL)	Number of Tested	Positive (+)	Negative (-)
0	25	0	25
12.5	25	0	25
18.8	25	0	25
25	25	0	25
31.3	25	18	7
37.5	25	25	0
50	25	25	0