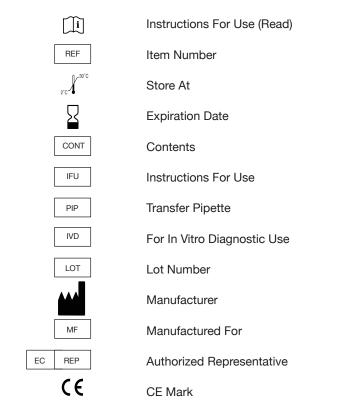
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Symbols Key



Status DS THC/OPI/COC/AMP/BZO/BAR/TCA/PCP

P-58181-D

One-Step Panel Test for Drugs of Abuse

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

Urine

For In Vitro Use Only

LifeSign, LLC

Item No. 28010 10 Test Kit Item No. 28025 25 Test Kit

Intended Use

Status DS 8 Panel (THC/OPI/COC/AMP/BZO/BAR/TCA/PCP) test is a simple, one-step immunochromatographic assay for the rapid, qualitative detection of opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, amphetamine, and/or their metabolites present in human urine at the cutoff concentration of the drug specified, see Expected Values.

Status DS 8Panel (THC/OPI/COC/AMP/BZO/BAR/TCA/PCP) 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

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 -carboxvlic 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

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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. 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 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test uses solid-phase chromatographic membrane immunoassay technology for the qualitative, simultaneous detection of opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, 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* 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test kit contains all the reagents necessary to perform the assay.

- Status DS 8 Panel(THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) 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-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, 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* 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) 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 μ L 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.

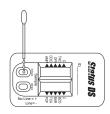
Specimens containing a large amount of particulate matter may give inconsistent test results. Such specimens should be clarified by centrifuging or allowing to settle before testing.

Test Procedure

The test procedure consists of adding the urine sample to the Sample well of the device and watching for the appearance of colored lines in the result window.

Test Protocol

- For each test, open one *Status DS* 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) pouch and label the *Status DS* device with the patient ID.
- 2. Holding the dropper vertically, dispense 3 drops (110 μ L) of the urine sample into the each Sample well (S).



COC Benzoylecgonine Cocaine HCI Ecgonine HCI	300 >100,000 >100,000
THC Cannabinol 11-hydroxy-Δ ⁹ -THC 11-nor-Δ ⁸ -THC-9-COOH 11-nor-Δ ⁹ -THC-9-COOH Δ ⁸ -THC Δ ⁹ -THC	>100,000 7,500 250 50 >100,000 >100,000
PCP Phencyclidine Thienylcyclohexyl-piperidine	25 450
Alprazolam Bromazepam Chlordiazepoxide Clobazam Clonazepam Clorazepate dipotassium Delorazepam N-Desalkylflurazepam Diazepam Estazolam Flunitrazepam 7-amino-flunitrazepam a-Hydroxyalprazolam a-Hydroxytriazolam Lorazepam Lornetazepam Medazepam Midazolam Nitrazepam Nordiazepam(N-Desmethyldiazepam) Oxazepam Prazepam Temazepam Temazepam Triazolam	100,000 1,250 500 >100,000 30,000 2,500 10,000 >100,000 1,500 2,500 100,000 100,000 100,000 25,000 10,000 25,000 100,000 100,000 100,000 >100,000 >100,000 >100,000 >100,000
BAR Allobarbital Alphenal Amobarbital Aprobarbital Barbital Butalbital Cyclopentobarbital Pentobarbital Phenobarbital Penytoin Secobarbital Thiopental	400 250 5,000 400 1,500 800 400 2,000 5,000 4,000 300 >100,000
Amitryptiline Chlorpromazine Clomipramine Cyclobenzaprine Desipramine Diphenhydramine Dothiepin Doxepin Imipramine Norclomipramine Norclomipramine Nortriptyline Perphenazine Promazine Protryptiline Trimipramine	800 100,000 5,000 2,500 11,500 >100,000 1,500 1,000 5,000 41,000 41,000 5,000 2,000 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
B-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** 8 PANEL

(MET/OPI/COC/THC/PCP/BZO/BAR/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 8 drugs.

Table 14. Endogenous Compounds

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

Exogenous compounds:

The following compounds showed no cross-reactivity when tested with the *Status DS* 8 PANEL (MET/OPI/COC/THC/PCP/BZO/BAR /TCA/AMP) at a concentration of 100 µg/mL. (Table 14.)

 Table 14. Non Cross-Reacting Compounds

-Acetamidophenol acetophenetidin (Phenacetin) I-Acetylprocainamide acetylsalicylic acid aminopyrine amoxapine amoxapine amoxicillin apomorphine aspartame atropine denzilic acid denzoic acid denzohetamine chloralhydrate chlorathydrate chlorathydrate chlorathydrate chlorothiazide chlorothiazi	Furoxmide Gentisic acid Glutethimide Guaifenesin Hippuric acid Hydralazine Hydrocortisone O-Hydroxyhippuric acid Iproniazid (-) Isoproterenol Isoxsuprine Ketoprofen Labetalol Lidocaine Loperamide Loxapine succinate Meprobamate Methaqualone Methoxyphenidate Methylphenidate Methylphenidate Methylphenidate Methyprylon Nalidixic acid Naltrexone Naproxen Niacinamide Nifedipine Norethindrone Noroxymorphone D-Norpropoxyphene (-) Norpseudoephedrine Noscapine Nylidrin D,L-Octopamine

Promethazine D,L-Propanolol Propiomazine D-Propoxyphene Quinidine Quinine Rantidine Salicylic acid Serotonin Sulfamethazine Sulindac Tetracycline Tetrahydrocortisone Tetrahvdrozoline Thiamine Thioridazine D,L-Thyroxine Tolbutamide Triamterene Trifluoperazine Trimethoprim D,L-Tryptophan D.L-Tyrosine Uric acid Verapamil

Zomepirac

Oxalic acid

Oxolinic acid

Papaverine

Penicillin-G

Phenelzine

Prednisone

Pentazocaine

Prednisolone

Phendimetrazine

Oxymetazoline

Precision

The precision of the Status DS 8 PANEL (THC/OPI/COC

/AMP/BZO/BAR/TCA/PCP) test was determined by two people on five different days with serially diluted solutions of 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 8 drugs. The results are summarized

Table 11 Draginian Chudy

Table 11. Precis	ion Study			
Opiates Test				
Drug Conc.	Number	Positive	Negative	Agreemen
(ng/mL)	of Tested	(+)	(-)	%
150	20	0	20	100
225	20	0	20	100
375	20	20	0	100
450	20	20	0	100
Cocaine Test				
Drug Conc.	Number	Positive	Negative	Agreemen
(ng/mL)	of Tested	(+)	(-)	%
150	20	0	20	100
225	20	0	20	100
375	20	20	0	100
450	20	20	0	100
THC Test				

(ng/mL)	of Tested	(+)	(-)	%
25	20	0	20	100
37.5	20	0	20	100
62.5	20	19	1	95
75	20	20	0	100

Positive

Negative Agreement

Number

Phencyclidine Test

Drug Conc.

Drug Conc.	Number	Positive	Negative	Agreemen
(ng/mL)	of Tested	(+)	(-)	%
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

225

375

450

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

0

19

20

20

1

0

100

95

100

20

20

20

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

Drug Conc.	Number	1 0311176	riegative	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

Negative Agreement

Concentration

Distribution of Random Error

Forty blind samples for each drug were prepared by spiking various concentrations of each of the 8 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 8 PANEL (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) 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 8 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 8 PANEL (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test. The specificity of the Status DS 8 PANEL (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test was determined by adding various drugs and drug metabolites to drug-negative urine specimens and testing with the Status DS 8 PANEL (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test. The results are expressed in terms of the minimum concentration required to produce a

Table 12. Specificity

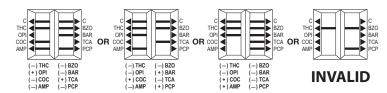
Compound

positive result (Table 12).

Compound	(ng/mL)
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

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 8 Panel test device. Examples of possible results are shown in the diagram above.

There are other possible results, depending on the combination of drugs 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 which are not listed in Tables 12 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 opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, 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 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) is a qualitative test. The amount of opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, 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 opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, amphetamine, and/or their metabolites above the cutoff concentration. The Status DS 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test has been shown to detect each drug with the following cutoff: 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, 1000 ng/mL of nortriptyline and 1000 ng/mL of amphetamine in urine.

Performance Characteristics

The accuracy of Status DS 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test was evaluated in comparison to a commercially available immunoassay Status DS OPI. Status DS COC. Status DS THC, Status DS PCP, Status DS BZO, Status DS BAR, 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 and 8. A complete agreement (100 %) was observed.

Table 1. Opiates Accuracy: Comparison of Status DS 8 Panel with Status DS OPI

Status DS (OPI)

Status DS 8 Panel (OPI)

		•	
	Positive	Negative	Total
Positive	150	0	150
Negative	0	200	200
Total	150	200	350

Table 2. Cocaine Accuracy: Comparison of *Status DS* 8 Panel with *Status DS* COC

Status DS (COC)

Status DS 8 Panel	
(COC)	

		Positive	Negative	Total
	Positive	150	0	150
	Negative	0	200	200
ĺ	Total	150	200	350

Table 3. THC Accuracy: Comparison of *Status DS* 8 Panel with *Status DS* THC

Status	DS (П	H	U
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Status DS 8 Panel	
(THC)	

	Positive	Negative	Total
Positive	150	0	150
Negative	0	200	200
Total	150	200	350

Table 4. Phencyclidine Accuracy: Comparison of *Status DS* 8 Panel with *Status DS* PCP *Status DS* (PCP)

Status DS 8 Panel
(PCP)

	Positive	Negative	Total
Positive	55	0	55
Negative	0	153	153
Total	55	153	208

Table 5. Benzodiazepine Accuracy: Comparison of *Status DS* 8 Panel with *Status DS* BZO

Status DS (BZO)

Status DS 8 Panel (BZO)

	Positive	Negative	Total
Positive	174	0	174
Negative	0	200	200
Total	174	200	374

Table 6. Barbiturate Accuracy: Comparison of *Status DS* 8 Panel with *Status DS* BAR

Status DS (BAR)

Status DS 8 Panel (BAR)

	Positive	Negative	Total
Positive	99	0	99
Negative	0	204	204
Total	99	204	303

Table 7. Tricyclic Antidepressant Accuracy: Comparison of *Status DS* 8 Panel with *Status DS* TCA

Status DS (TCA)

Status DS 8 Panel (TCA)

	Positive	Negative	Total
Positive	103	0	103
Negative	0	207	207
Total	103	207	310

Table 8. Amphetamine Accuracy: Comparison of $\it Status DS 8$ Panel with $\it Status DS AMP$

Status DS (AMP)

Status DS 8 Panel (AMP)

	Positive	Negative	Total
Positive	98	0	98
Negative	0	200	200
Total	98	200	298

In a separate study, *Status DS* 8 Panel (THC/OPI/COC /AMP/BZO/BAR/TCA/PCP) test was evaluated against specimens confirmed as positive by GC/MS, for each of the 8 drugs. The results are shown in Table 9.

Table 9. Comparison of Status DS 8 Panel with GC/MS Assay

	Concentration (GC/MS value) ng/mL	Number of Samples	8 Panel
Methamphetamine	14630-05227	15	15
	706, 750, 770, 860	4	4
Morphine	36 - 172440	31	31
	192, 215, 226, 230	4	4
Benzoylecgonine	371 - 64800	41	41
	220, 220, 224, 225, 271	5	5
Δ ⁹ -THC-9-COOH	73 - 910	37	37
	34, 36, 37, 38, 39	5	5
PCP	40 - 97	21	21
	17, 18, 18	3	3
Oxazepam	370 - 8641	28	28
	210, 225, 230	3	3
Secobarbita	324 - 14560	23	23
	200, 225, 230	3	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, cutoff, 25% above cutoff, 50% above cutoff and 100% above cutoff. The results of the sensitivity studies are summarized below.

Table 10. Validation of cut-off level for Status DS 8 PANEL

Drug Standards and Cutoff Values for Each Drug Test

Test Name	Drug Standard	Cutoff Conc.(ng/mL)		
Opiates	Morphine	300		
Cocaine	Benzoylecgonine	300		
THC	11-nor-∆9-THC-9-COOŀ	H 50		
Phencyclidine	Phencyclidine	25		
Benzodiazepine	Oxazepam	300		
Barbiturate	Secobarbital	300		
Tricyclic Antidepressant	Nortriptyline	1000		
Amphetamine	D-Amphetamine	1000		

Opiates Test				Benzodiazepine Test			
Drug Conc.	Number	Positive	Negative	Drug Conc.	Number	Positive	Negative
(ng/mL)	of Tested	(+)	(-)	(ng/mL)	of Tested	(+)	(-)
0	25	0	25	0	25	0	25
150	25	0	25	150	25	0	25
225	25	0	25	225	25	0	25
300	25	0	25	300	25	0	25
375	25	24	1	375	25	22	3
450	25	25	0	450	25	25	0
600	25	25	0	600	25	25	0
Cocaine Test				Barbiturate Test			
Drug Conc.	Number	Positive	Negative	Drug Conc.	Number	Positive	Negative
(ng/mL)	of Tested	(+)	(-)	(ng/mL)	of Tested	(+)	(-)
0	25	0	25	0	25	0	25
150	25	0	25	150	25	0	25
225	25	0	25	225	25	0	25
300	25	0	25	300	25	0	25
375	25	22	3	375	25	22	3
450	25	25	0	450	25	25	0
600	25	25	0	600	25	25	0
THC Test				Tricyclic Antidepressar	nt Test		
Drug Conc.	Number	Positive	Negative	Drug Conc.	Number	Positive	Negative
(ng/mL)	of Tested	(+)	(-)	(ng/mL)	of Tested	(+)	(-)
0	25	0	25	0	25	0	25
25	25	0	25	500	25	0	25
37.5	25	0	25	750	25	0	25
50	25	0	25	1000	25	0	25
62.5	25	22	3	1250	25	24	1
75	25	25	0	1500	25	25	0
100	25	25	0	2000	25	25	0
Phencyclidine Test				Amphetamine Test			
Drug Conc.	Number	Positive	Negative	Drug Conc.	Number	Positive	Negative
(ng/mL)	of Tested	(+)	(-)	(ng/mL)	of Tested	(+)	(-)
0	25	0	25	0	25	0	25
12.5	25	0	25	500	25	0	25
18.8	25	0	25	750	25	0	25
25	25	0	25	1000	25	0	25
31.3	25 25	18	7	1250	25	20	5
37.5 50	25 25	25 25	0	1500	25	25	0
50	20	20	U	2000	25	25	0

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