lifeSign

CLSI PROCEDURE

Product Name: **Status DS**	
Item Number: 21025, 21010	**Non-Waived**

Institution:	
Prepared By:	Date:
Title:	

Accepted By:	Date:
Title:	

Accepted By:		Date:	

Discontinued By	Date:

CONTENTS

SECTION 1 - TEST NAME

Status DS

One-Step Panel Assay for Drugs of Abuse

SECTION 2 - INTENDED USAGE

Status DS 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, (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) and/or their metabolites present in human urine.
Cutoff levels for Status DS drugs are as follows:

Test Name	Drug Standard	Cutoff Conc. (ng/ML)
THC	11-nor-Δ^9-THC-9carboxylic 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
PCP	Phencyclidine	25 ng/mL
BZO	Oxazepam	300 ng/mL
BAR	Secobarbital	300 ng/mL
MTD	Methadone	300 ng/mL
TCA	Nortriptyline	1000 ng/mL

SECTION 3 - SUMMARY AND EXPLANATION OF TEST

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 (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.[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 (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, papillary 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 deaminatedderivatives.[3,6]

SECTION 4 - PRINCIPLE OF TEST

The **Status DS** 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 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) 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.

SECTION 5 - KIT CONTENTS AND STORAGE

- **Status DS** test devices (10, 25 or 35)
- Disposable sample dispenser
- Package insert

STORAGE REQUIREMENTS:

The **Status DS** 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.

SECTION 6 - MATERIALS REQUIRED BUT NOT PROVIDED

- Urine collection container
- Refrigerator if testing will not be performed within 2 hours
- Timer
- Latex Gloves

SECTION 7 - WARNINGS AND 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.
• The 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 **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.

SECTION 8 - PATIENT PREPARATIONS AND SPECIMEN COLLECTION

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) for up to 48 hours. If longer storage is required, specimen may be stored frozen (-20°C or colder). 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.

SECTION 9 - QUALITY CONTROL AND ASSURANCE

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.

SECTION 10 - TEST PROCEDURE

Bring **Status DS** test device and urine to room temperature before use if refrigerated:

1. For each test, open one Status DS 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 Sample well (S).
3. Read the result after 5 minutes, but within 10 minutes of sample addition.

SECTION 11 - INTERPRETATION OF RESULTS

Negative:

The appearance of a reddish-purple Control line (C) and a line for a specific drug indicate 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

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.

The **Status DS** 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]

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** test device.

SECTION 12 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 Table 1 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.
- The following table lists compounds that are detected by the **Status DS** test. The specificity of the **Status DS** test was determined by adding various drugs and drug metabolites to drug-negative urine specimens and testing with the **Status DS** test kit. The results are expressed in terms of the minimum concentration required to produce a positive result.

Table 1. Specificity

Compound	Concentration (ng/mL)
MET	
D-Amphetamine	>100,000
D,L-Amphetamine	>100,000
(−)Ephedrine	>100,000
(±)Ephedrine	>100,000
Isometheptene	12,500
D-Methamphetamine	1,000
p-OH-Methamphetamine	3,000
Methylenedioxyamphetamine	>100,000
Methylenedioxyethylamphetamine (MDEA)	100,000
Methylenedioxymethamphetamine	1,000
OPI	
Codeine	300
Hydrocodone	500
Hydromorphone	500
Lavofloxacin	100,000
Levophanol	5,000
Meperidine	>100,000
Morphine	300
Morphine-3-ß-D-glucuronide	300
Nalorphine	15,000
Naloxine	>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	10,000
11-hydroxy- □Δ^{9}-THC	4,000
11-nor-Δ^{8}-THC-9-COOH	100
11-nor-□Δ ^{9}-THC-9-COOH	50
Δ ^{8}-THC	10,000
Δ ^{9}-THC	5,000
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
α -Hydroxyalprazolam	100,000
α -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
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	37,000
Benzphetamine	>100,000
D-Methamphetamine	>100,000
p-OH-Methamphetamine	>100,000
Methylenedioxyamphetamine	2,000
Methlyenedioxymethamphetamine	>100,000
ß-Phenethylamine	40,000
L-Phenylpropanolamine	>100,000
Phentermine	>100,000
Tryptamine	50,000
Tyramine	70,000
3-OH-Tyramine	>50,000

SECTION 13 EXPECTED RESULTS

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.

SECTION 14 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		
Status DS 10 Panel (MET)	Positive	Negative	Total
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)		
Status DS 10 Panel (OPI)	Positive	Negative	Total
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)		
Status DS 10 Panel (COC)	Positive	Negative	Total
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)		
Status DS 10 Panel (THC)	Positive	Negative	Total
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)		
Status DS 10 Panel (PCP)	Positive	Negative	Total
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)		
Status DS 10 Panel (BZO)	Positive	Negative	Total
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)		
Status DS 10 Panel (BAR)	Positive	Negative	Total
Positive	99	0	99
Negative	0	204	204
Total	99	204	304

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

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

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

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

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	1463-5227 706, 750, 770, 860	15 4	+ –
Morphine	36 - 172440 192, 215, 226, 230	31 4	+ –
Benzoylecgonine	371 - 64800 220, 220, 224, 225, 271	41 5	+ –
11-nor ⊗9-THC-9-COOH	73 - 910 34, 36, 37, 38, 39	37 5	+ –
PCP	40 - 97 17, 18, 18	21 3	+ –
Oxazepam	370 - 8641 210, 225, 230	28 3	+ –
Secobarbita	324 - 14560 200, 225, 230	23 3	+ –
Methadone	307 - 6523 183, 220, 225	43 3	+ –
TCA - Nortriptyline	1119 - 11140 700, 750, 852, 870	19 4	+ –
Amitriptyline	1269 - 16000 717, 824, 847, 866, 870, 780	40 6	+ –

For Sensitivity, Precision, Distribution of Random Error, Reproducibility, Specificity and Interfering Substances refer to the Package Insert.

SECTION 165 REFERENCECES

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8. Bickel MH. Poisoning by Tricyclic Antidepressant Drugs. Int. J. Clinical Pharmacol. 11 (1975) 145-176 (No. 2).

SECTION 16 TECHNICAL ASSISTANCE

For technical assistance, contact LifeSign Technical Service Department at 1-800-526-2125

Helpful CLIA brochure links to explain Clinical Laboratory Improvement Amendments (CLIA) regulation requirements

Individualized Quality Control Plan- IQCP

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure11.pdf

Proficiency Testing

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf

Proficiency Testing Providers

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf

Personnel Competency Assessment

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

Corrective Action Form

Problem /Error	Corrective Action

Laboratory Technologist: _____ Date: _____

Laboratory Director: _____ Date: _____

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Certification of Training

This is to verify that personnel responsible for running _____ test at _____ have been thoroughly in-serviced on the test and the test procedure(s).

This has included:

Review of the package insert
Demonstration of the product assay
Successful performance of the test and interpretation of results

Names of the personnel who have been trained with the above test and are responsible for reporting patient results:

Print Name	Signature	Date

Signature(s) of those responsible for personnel and testing:

_____ Signature _____ Date

_____ Signature _____ Date

_____ Signature _____ Date

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Test Validation Form

Account Name: _____

Address: _____

_____

Telephone: _____

Test Name: _____ Lot # : _____

Start Date: _____

Supervisor Signature: _____

Sample Number	Expected Results	Test Result	Tester's Initials	Comments

Reviewed by: _____

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Quality Control

Name of Facility _____

Use this cover sheet with each new shipment and/or with each new kit lot

Product _____ Lot# _____ Exp Date _____

Date Received _____ Rec'd By _____

	Date	Positive Control	Negative Control	Initials
Initial QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				

Reviewed by _____ Date _____

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Testing Personnel Competency Assessment

Test _____

Procedure	Satisfactory	Unsatisfactory	Not Applicable	Comments/Corrective Action(s)
Observation of Test performance				
Patient Sample Preparation				
Specimen Handling/Processing				
Testing				
Recording/Reporting Results				
Assessment of Test Performance Using Known Samples				
Review of Records				
Patient/Quality Control Log Sheet Records				
Proficiency Testing Records				
Assessment of Problem Solving Skills				

(Attach all supporting documents)

Evaluator: _____ Date: _____

Testing Personnel: _____ Date: _____