P-58150

*Status*First™ DOA 10

(MET/OPI/COC/THC/PCP/ BZO/BAR/MTD/TCA/AMP)

*Status*First™ DOA 5

(MET/OPI/COC/THC/PCP)

New One-Step Panel Test for Drugs of Abuse with DXpress® Reader

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

Stock No.	DOA 10	30025	25 Test Kit
		30010	10 Test Kit
	DOA 5	30525	25 Test Kit

Intended Use

*Status*First™ DOA 10 test is a simple, one-step immunochromatographic assay for the rapid, qualitative detection of methamphetamine, opiates, cocaine metabolites, THC metabolites, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants, amphetamine, and/or their metabolites present in human urine above the cutoff concentration of the drug specified. *Status*First™ DOA 5 test detects methamphetamine, opiates, cocaine metabolites, THC metabolites, phencyclidine, and/or their metabolites.

The Status*First™ DOA 10/DOA 5 *test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or HPLC (for TCA) 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 obtained.[2]

Summary and Explanation

Methamphetamine (MET) 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 **(OPI).** 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 (COC), 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 (PCP) 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 (BZO) 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 (BAR) 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, seizures, and death. 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 is generally excreted as metabolites, while long-acting ones primarily appear unchanged.[2,3]

Methadone (MTD) 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. Over dosage 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 over dosage 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 (AMP) 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*First™ DOA 10/DOA 5 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 to bind to the antibodies between the drug conjugates and the drugs which may be present in the urine sample. In the test procedure, a sample of urine is placed in the Sample well of the device and is allowed to migrate upward. If the drug is present in the urine sample, it competes with the drug conjugate, which is bound to the dye, for the limited antibodies immobilized on the membrane. If the drug or drug metabolite levels are 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 in the test window, indicating a positive result from positive drug competition, while a negative urine sample will generate a line in the test window, indicating a negative result from an absence of competition with free drugs.

In addition to the Test line that may appear in the Test window (T), a Control line is present in the Control window (C) 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 antibody is immobilized on the control line. The monoclonal antibody-dye conjugates that pass the region will be captured and produce a colored line in the Control window (validation line). 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. If insufficient sample volume is used, there may not be a Control line, indicating the test is invalid.

Materials Provided

The *Status*First™ DOA 10/DOA 5 test kit contains all the reagents necessary to perform the assay.

- *Status*First™ DOA 10/DOA 5 device. The test device contains membrane strips and dye pads: Membrane strips are coated with THC-protein (from a purified bovine protein source) conjugate, PCP-protein (from a purified bovine protein source) conjugate, monoclonal anti-methamphetamine, anti-morphine, anti-benzoylecgonine, anti-barbiturate and anti-amphetamine antibodies, as well as polyclonal sheep anti-oxazepam, anti-methadone and anti-tricyclic antidepressant antibodies. Sheep anti-mouse antibody is coated for the control bands. 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 purified bovine source protein).
- Disposable sample dispenser.
- Instructions for use.

Precaution

- 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*First™ 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*First™ DOA 10/DOA 5 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

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 settling before testing.

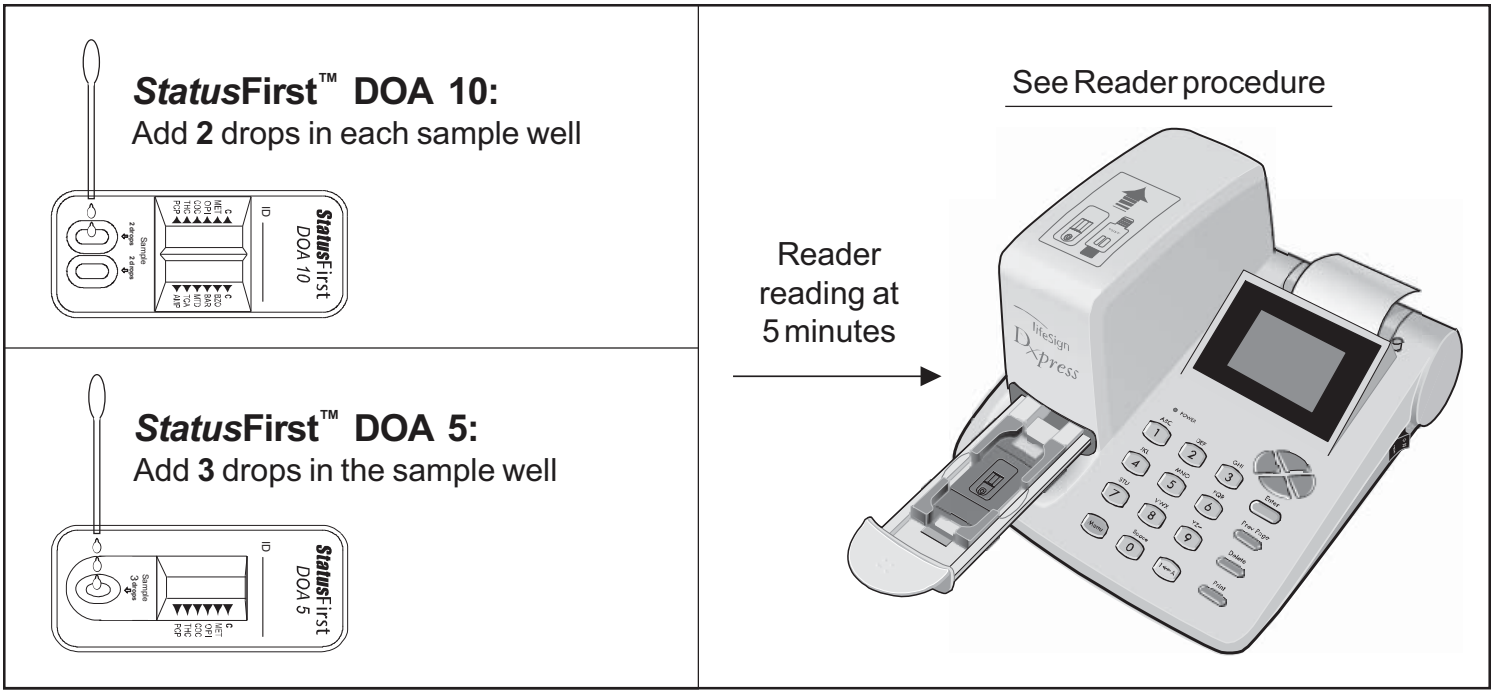
Test Procedure

The test procedure consists of adding the urine sample to the Sample well of the device and reading the test result at 5 min after sample addition using a DXpress™ Reader.

DXpress™ Reader Procedure

Consult the DXpress™ Reader User Manual.

For DXpress™ Reader installation, start up and complete instructions refer to the DXpress™ Reader User Manual. Operator must consult the DXpress™ Reader User Manual prior to use and become familiar with the processes and quality control procedures.



Performing Self Check

Each time the DXpress™ Reader is turned on, Self Check is automatically performed and the operator may then proceed to "**Performing Calibration QC"**. If the DXpress™ Reader is left on or in power save mode, the operator should perform Self Check daily as follows:

1. From the Main Menu, select **[2] RUN QC**
2. Select **[1] SELF CHECK**
3. Self Check takes about 15 seconds. **PASS** or **FAIL** results will be displayed/printed when testing is completed. All Self Check items should pass before testing patient samples.
4. Press **ENTER** from the Self Check result screen to return to the **RUN QC** menu; proceed to Step 2 of "**Performing Calibration QC".**

Performing Calibration QC

Each day of patient testing, use the QC Calibration Set (see DXpress™ Reader manual) to ensure the DXpress™ Reader functions properly:

1. From the Main Menu, select **[2] RUN QC**
2. Select **[2] CALIBRATION QC**
3. Either input Operator ID manually and press **ENTER** or scan Operator ID barcode.
4. Scan the QC Calibrator ID barcode, found on the back of the QC Calibrator.
5. Insert the QC Calibrator into the reader – be sure to close the Tray – and press **ENTER**. Follow prompts displayed on the screen.
6. A **CALIBRATION OK** result will be displayed/printed when the calibration is completed. Press **ENTER** to perform **"Blank Calibration".**
7. Select **CALIBRATE**, and press **ENTER**.
8. Select **Double Window Cassette**, and press **ENTER**.
8. Insert a Blank Calibrator double window device, and press **ENTER**. Reader will display "**Successfully Performed**."
9. Press **ENTER** to return to the Main Menu.

Calibration should succeed before running daily patient testing.

Running QC with External Controls

The manufacturer recommends the use of commercially available controls.

1. From Main Menu, select **[2] RUN QC**
2. Select **[3] EXTERNAL QC**
3. Follow the same procedure as if running a patient sample; please see section "**Testing Patient Samples"** below. The only difference is that **RUN PATIENT** requires a Patient ID, whereas **EXTERNAL QC** requires a Sample ID.

Testing Patient Samples

Patient samples may be tested using the DXpress™ Reader Scheduler mode, as described below. To use other modes (batch mode or read-now mode) please consult the DXpress™ Reader User Manual.

1. Open the pouch and remove the test device.
2. Label the patient ID on the test device with a permanent marker.
3. Place the test device on a level surface.
4. Testing the Patient Sample on the DXpress™ Reader:

- From the Main Menu, select **[1] RUN PATIENT**
- Scan lot number barcode from the pouch or kit box.
- Confirm test device information (lot number and type of test device) as displayed on the screen and press **ENTER**
- Scan the Operator ID barcode (or manually enter).
- Scan the Patient ID barcode (or manually enter).
- From the Incubation Time window, select **SCHEDULER**
- Add patient sample to test device by holding the dropper in a vertical position and dispense

  2 drops for ***Status*First™ DOA 10** or
  3 drops for ***Status*First™ DOA 5**

  of sample into **EACH** sample well. When drawing sample into the dropper, avoid introducing air bubbles. Do not touch the sample well or test device with the tip of the dropper.
- Immediately press **ENTER**
- Insert the test device in the Reader tray, close the Reader tray.
- After 5 minutes of incubation the DXpress™ Reader will automatically read and display the results on the screen.

NOTE: *To view results of all drugs, press [Left] and [Right] navigation key to switch between the left and right windows. Pressing [PRINT] will print results for both windows in one step.*

Report of Results

The result of positive or negative for each analyte is detrmined by the DXpress™ Reader.

- Results may be printed by pressing the **PRINT** button.
- At this point the test device may be removed and appropriately discarded.

Result Example

Control: Valid	Control: Valid
MET: Negative	BZO: Negative
OPI: Positive	BAR: Negative
COC: Negative	MTD: Negative
THC: Negative	TCA: Positive
PCP: Negative	AMP: Negative

Invalid

The instrument will automatically determine the control line is not present.

If the result is invalid, the sample should be retested with a new device. If the problem persists, contact your local distributor of LifeSign.

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 11 below, may interfere with the test and cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, the test should be repeated with a new sample.
- Certain foods or medications containing opiates or opiate derivatives, amphetamins, methamphetamine, barbiturate, benzodiazepines, or tricyclics may produce a positive result in any chemical or immunological assay. Poppy seeds can contain opiates and ingestion of products containing poppy seeds can cause a positive result.
- The test result read after 5 minutes may not be consistent with the original reading obtained at 5 minute reading period. The test must be read at 5 minutes of sample application.
- 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.
- 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.

User Quality Control

Internal Control: Each *Status*First™ test device has a built-in control. The Control line is an internal positive process control. A distinct reddish-purple Control line should always appear in the 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 working. In addition, if the test has been 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 process control. The DXpress Reader will report "Control: Valid" and test results when Internal Control QC is satisfied.

The positive and negative process controls contained in each *Status*First™ 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 window, 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 and assay procedure are performing properly. It is recommended that a control be tested at regular intervals as good laboratory testing process. For information on how to obtain controls, contact LifeSign's Technical Services.

Expected Values

*Status*First™ DOA 10/DOA 5 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*First™ DOA 10/DOA 5 test has been shown to detect each drug at 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

Accuracy

The accuracy of *Status*First™ DOA 10/DOA 5 was evaluated in comparison to the result of GC/MS (HPLC for TCA). For each drug, over 60 clinical samples containing some amount of the drug were tested and the results were compared to the GC/MS or HPLC values. In addition, 100 drug-free urine samples were collected from people who apparently were not taking the drug and were tested.

The summary of results is shown in Table 1.

Table 1. The Results Summary of Comparison Study to Reference Method (GC/MS or HPLC) with Clinical Samples

† Clinical samples were grouped A through E based on each drug concentration as shown below:

A: Drug-free

B: Negative (between 0 and 50% cutoff)

C: Negative (between 50% cutoff and cutoff)

D: Cutoff (between cutoff and 150% cutoff)

E: Positive (≥150% cutoff)

Drug	Result \ Drug Conc. Range†	A	B	C	D	E	% Agreement with Reference Test
THC	Pos.	0	0	0	11	40	98 (51/52)
	Neg.	100	7	10	0	1	100 (117/117)
OPI	Pos.	0	1	4	8	49	100 (57/57)
	Neg.	100	15	8	0	0	96 (123/128)
COC	Pos.	0	0	2	5	47	98 (52/53)
	Neg.	100	13	11	1	0	98 (124/126)
MET	Pos.	0	0	6	6	42	98 (48/49)
	Neg.	100	14	5	1	0	95 (119/125)
PCP	Pos.	0	0	0	14	49	95 (63/66)
	Neg.	100	6	9	1	2	100 (115/115)
BZO	Pos.	0	0	3	6	53	100 (59/59)
	Neg.	100	7	7	0	0	97 (114/117)
BAR	Pos.	0	0	0	4	42	98 (46/47)
	Neg.	100	10	8	1	0	100 (118/118)
MTD	Pos.	0	0	1	6	71	99 (77/78)
	Neg.	100	10	8	0	1	99 (118/119)
TCA	Pos.	0	0	0	5	36	100 (41/41)
	Neg.	100	11	9	0	0	100 (120/120)
AMP	Pos.	0	0	1	8	39	96 (47/49)
	Neg.	100	16	13	2	0	99 (129/130)

Precision and Cutoff Validation Study

For the precision and cutoff value validation of each drug test on the panel, spiked urine controls with concentrations of 0, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff, 50% above cutoff and 100 % above cutoff levels were tested. Ten (10) devices at each concentration were tested on three readers for two days with two lots of test devices by three operators blindly. The summary of the results are shown in table 2.

All test results with the samples of negative or 100% above cutoff level agreed with expected results in both reader and visual reading. With ±50% cut off level the results showed from 98 to 100% agreements with expected results. There were no significant differences between device lots and days.

Table 2. Precision Study for *Status*First™ DOA 10/DOA 5

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

***+/–: # of Pos./# of Neg.**

Methamphetamine Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
500	120	0/120	100
750	120	22/98	82
1000	120	73/47	N/A
1250	120	113/7	94
1500	120	119/1	99
2000	120	120/0	100

Opiates Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
150	120	0/120	100
225	120	1/119	99
300	120	58/62	N/A
375	120	99/21	83
450	120	117/3	98
600	120	120/0	100

Cocaine Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
150	120	1/119	99
225	120	30/90	75
300	120	83/37	N/A
375	120	111/9	93
450	120	120/0	100
600	120	120/0	100

THC Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
25	120	0/120	100
37.5	120	9/111	93
50	120	72/48	N/A
62.5	120	109/11	91
75	120	117/3	98
100	120	120/0	100

Phencyclidine Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
12.5	120	0/120	100
18.8	120	6/114	95
25	120	68/52	N/A
31.3	120	117/3	98
37.5	120	119/1	99
50	120	120/0	100

Benzodiazepine Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
150	120	0/120	100
225	120	24/96	80
300	120	77/43	N/A
375	120	110/10	92
450	120	120/0	100
600	120	120/0	100

Barbiturate Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
150	120	3/117	98
225	120	27/93	78
300	120	81/39	N/A
375	120	110/10	92
450	120	120/0	100
600	120	120/0	100

Methadone Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
150	120	2/118	98
225	120	32/88	73
300	120	90/30	N/A
375	120	112/8	93
450	120	119/1	99
600	120	120/0	100

Tricyclic Antidepressant Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
500	120	0/120	100
750	120	5/115	96
1000	120	63/57	N/A
1250	120	101/19	84
1500	120	119/1	99
2000	120	120/0	100

Amphetamine Test

Drug Conc. (ng/mL)	# Tested	+/–*	% Agreement
0	120	0/120	100
500	120	1/119	99
750	120	27/93	78
1000	120	92/28	N/A
1250	120	116/4	97
1500	120	118/2	98
2000	120	120/0	100

Reproducibility

0.5X cutoff, and 2X cutoff levels of each of 10 drugs' samples were prepared by spiking each drug standard solution into the drug negative urine. The prepared samples including negative urine were aliquoted for each test and given blindly to each site. Thirty (30) tests for each drug (10 tests at each concentration) for a total of 300 tests per site were tested at three POL sites. Results demonstrated 99 % (895 out of 900 tests) agreement among the three sites.

Specificity

The following table lists compounds that were evaluated with the *Status*First™ DOA 10/DOA 5 test for specificity. The specificity of the *Status*First™ DOA 10 test was determined by adding various drugs and drug metabolites to drug-negative urine specimens and testing with the *Status*First™ DOA 10/DOA 5 test. The results are expressed in terms of the minimum concentration required to produce a positive result (Table 3).

Table 3. Specificity

Compound	Cross-reacting 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
Methylenedioxymethamphetamine	1,000
Methylenedioxyethylamphetamine(MDEA)	>100,000
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	10,000
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
11-hydroxy-Δ^9-THC	4,000
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
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
l-Phenylpropanolamine	>100,000
Phentermine	>100,000
Tryptamine	50,000
Tyramine	70,000
3-OH-Tyramine	50,000

Interfering Substances

Endogenous compounds:
The *Status*First™ DOA 10/DOA 5 test showed no interference when the endogenous compounds were added at the concentrations given below to urine samples which had ± 50 % cutoff concentration of each of the 10 drugs (Table 4).

Table 4. Endogenous Compounds

Substance Added	Concentration Added
Bilirubin	2 mg/dl
Creatinine	20 mg/dl
Glucose	1500 mg/dl
Hemoglobin	25 mg/dl
Protein	2000 mg/dl
Sodium Chloride	1500 mg/ml
Sodium Nitrite	100 mg/dl

Exogenous compounds:
The following compounds show no interference when tested with the *Status*First™ DOA 10/DOA 5 at a concentration of 100 µg/mL (Table 5).

Table 5. Non Cross-Reacting Compounds

4-Acetamidophenol	Ethyl-p-aminobenzoate
Acetophenetidin (Phenacetin)	Fenoprofen
N-Acetylprocainamide	Furoxmide
Acetylsalicylic acid	Gentisic acid
Aminopyrine	Glutethimide
Amoxapine	Guaifenesin
Amoxicillin	Hippuric acid
Apomorphine	Hydralazine
Aspartame	Hydrochlorothiazide
Atropine	Hydrocortisone
Benzilic acid	O-Hydroxyhippuric acid
Benzoic acid	Iproniazid
Chloralhydrate	(–) Isoproterenol
Chloramphenicol	Isoxsuprine
Chlorothiazide	Ketoprofen
Chlorquine	Labetalol
Cholesterol	Lidocaine
Clonidine	Loperamide
Cortisone	Loxapine succinate
(–) Cotinine	Meprobamate
Deoxycorticosterone	Methaqualone
Dextromethorphan	Methoxyphenamine
Diclofenac	Methylphenidate
Diethylpropion	Methyprylon
Diflunisal	Nalidixic acid
Digoxin	Naltrexone
Domperidone	Naproxen
Doxylamine	Niacinamide
Erythromycin	Nifedipine
ß-Estradiol	Norethindrone
Estrone-3-sulfate	Noroxymorphone

D-Norpropoxyphene
(–)Norpseudoephedrine
Noscapine
Nylidrin
D,L-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocaine
Phendimetrazine
Phenelzine
Phentoin
Prednisolone
Prednisone
Promethazine
D,L-Propanolol
Propiomazine
D-Propoxyphene
Quinidine
Quinine
Rantidine
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone
Tetrahydrozoline
Thiamine
Thioridazine
D,L-Thyroxine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
D,L-Tryptophan
D,L-Tyrosine
Uric acid
Verapamil
Zomepirac

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Symbols Key

LOT — Lot Number	PIP — Transfer Pipette
Expiration Date	CE Mark
2°C 30°C — Store at 2-30°C	EC REP — Authorized Representative
Do Not Reuse	CONT — Contents
IVD — For *in vitro* Diagnostic Use	DEV — Test Device
REF — Catalog Number	Consult Instructions For Use
Manufacturer	
IFU — Instructions For Use	
Σ n — Contains sufficient for <n> tests	

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