

**Procedure:** Status DS

Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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**PRINCIPLE:**

The Status DS<sup>®</sup> 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) test uses solid-phase chromatographic membrane immunoassay technology for the qualitative, simultaneous detection of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, methadone, tricyclic antidepressants, and amphetamine in human urine. The test is based on the principle of the highly specific immunochemical reactions between antigens and antibodies which are used for the analysis of specific substances in biological fluids. The test relies on the competition 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 (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 at the Control (C) position (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.

**SPECIMEN:**

Approximately 110 µL of urine sample is required for each test sample well. Fresh urine specimens do not require any special handling or pretreatment. Specimens should be collected in a clean glass or plastic container. If testing will not be performed immediately, specimens should be refrigerated (2–8°C) or frozen. Frozen specimens must be completely thawed, and thoroughly mixed before using.

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

**EQUIPMENT AND MATERIALS:****Materials provided:**

The Status DS<sup>®</sup> 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) test kit contains all the reagents necessary to perform the assay.

- Status DS<sup>®</sup> 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) device. The test device contains membrane strips and dye pads: Membrane strips are coated with THC-protein (from a purified bovine protein source) conjugate, PCP-protein (from a purified bovine protein source) conjugate, monoclonal anti-methamphetamine, anti-morphine, anti-benzoyllecgonine, 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 band. Dye pads contain colloidal gold coated with monoclonal anti-THC, anti-phencyclidine, and mouse IgG antibodies as well as conjugates of methamphetamine, morphine, benzoyllecgonine, oxazepam, barbiturate, methadone, nortriptyline analogue and amphetamine (each drug is conjugated with purified bovine source protein).
- Disposable sample dispenser.
- Instructions for use.

**Storage Requirements:**

The Status DS<sup>®</sup> 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) test kit should be stored at 2–30°C (35–86°F) in the original sealed pouch. The expiration dating was established under these storage conditions.

**QUALITY CONTROL:**

**Internal Control:** Each Status DS<sup>®</sup> 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 at the C 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 positive and negative process controls contained in each Status DS<sup>®</sup> 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 at the C 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 and assay procedure are performing properly. 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 Technical Services.

### PROCEDURE - STEPWISE:

1. For each test, open one Status DS<sup>®</sup> 10 Panel (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP) pouch and label the Status DS<sup>®</sup> device with the patient ID.
2. Holding the dropper vertically, dispense 3 drops (110 µL) of the urine sample into each Sample well (S).
3. Read the result after 5 minutes, but within 10 minutes of sample addition.

### REPORTING RESULTS:

#### Interpretation of results:

**Negative:** The appearance of a reddish-purple Control line (C) and a line for a specific drug indicates a negative test result; i.e., no drug above the cutoff level has been detected. 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.*

**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<sup>®</sup> 10 Panel test device.

Cutoff Levels for Status DS drugs and their metabolites are as follows:

Test Name	Drug Standard	Cutoff Conc.(ng/mL)
Methamphetamine	d-Methamphetamine	1000
Opiates	Morphine	300
Cocaine	Benzoyllecgonine	300
THC	11-nor- $\Delta^9$ -THC-9-COOH	50
Phencyclidine	Phencyclidine	25
Benzodiazepine	Oxazepam	300
Barbiturate	Secobarbital	300
Methadone	Methadone	300
Tricyclic Antidepressant	Nortriptyline	1000
Amphetamine	d-Amphetamine	1000

**NOTE:** *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.*<sup>1</sup>

#### LIMITATIONS OF THE PROCEDURE:

- 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 concentration required to produce a positive result.

**Table 1. Specificity**

<b>Compound</b>	<b>Specificity Concentration (ng/mL)</b>
<b>MET</b>	
D-Amphetamine	200,000
D,L-Amphetamine	>200,000
(-)-Ephedrine	>200,000
(±)Ephedrine	200,000
D-Methamphetamine	1,000
p-OH-Methamphetamine	>200,000
Methylenedioxyamphetamine	>200,000
Methylenedioxymethamphetamine	2,000
Ofloxacin	200,000
<b>OPI</b>	
Codeine	300
Hydrocodone	500
Hydromorphone	600
Levophanol	5,000
Meperidine	80,000
Morphine	300

<b>Specificity Compound</b>	<b>Concentration (ng/mL)</b>
Morphine-3-β-D-glucuronide	500
Nalorphine	1,000
Naloxane	100,000
Norcodeine	60,000
Oxycodone	20,000
Oxymorphone	60,000
Procaine HCl	100,000
Thebaine	5,000
<b>COC</b>	
Benzoylcegonine	300
Cocaine HCl	300
Ecgonine HCl	>100,000
<b>THC</b>	
Cannabinol	50,000
11-nor-Δ <sup>8</sup> -THC-9-COOH	250
11-nor-Δ <sup>9</sup> -THC-9-COOH	50
Δ <sup>8</sup> -THC	25,000
Δ <sup>9</sup> -THC	15,000
11-hydroxy-Δ <sup>9</sup> -THC	10,000
<b>PCP</b>	
Dextormehorphan	900
Ofloxacin	62,500
Phencyclidine	25
Thienylcyclohexyl-piperidine	2500
<b>BZO</b>	
Alprazolam	10,000
Bromazepam	2,500
Chlordiazepoxide	1,000
Clobazam	10,000
Clonazepam	10,000
Clorazepate dipotassium	250
Delorazepam	1,000
N-Desalkylflurazepam	1,250
Diazepam	2,000
Estazolam	500
Flunitrazepam	>10,000
7 Amino Flunitrazepam	4,000
α-Hydroxyalprazolam	250
α-Hydroxytriazolam	2,500
Lorazepam	750
Lormetazepam	8,000
Medazepam	2,500
Midazolam	4,000
Nitrazepam	2,500
Nordiazepam (N-Desmethyldiazepam)	500
Ofloxacin	75,000
Oxazepam	300

<b>Specificity Compound</b>	<b>Concentration (ng/mL)</b>
Prazepam	9,000
Temazepam	800
Triazolam	>10,000
<b>BAR</b>	
Allobarbital	500
Alphenal	400
Amobarbital	2,000
Aprobarbital	200
Barbital	1,500
Butalbital	200
Cyclopentobarbital	500
Pentobarbital	1,000
Phenobarbital	3,000
Phenytoin	5,000
Secobarbital	300
Thiopental	>100,000
<b>MTD</b>	
Diphenhydramine	100,000
Doxylamine	>100,000
EDDP	>100,000
EMDP	>100,000
Imipramine	>100,000
LAAM	2,000
Methadone	300
Meperidine	>100,000
Nor-LAAM	10,000
<b>TCA</b>	
Amitryptiline	1000
Chlorpromazine	85000
Clomipramine	7500
Cyclobenzaprine	1500
Desipramine	1000
Diphenhydramine	150,000
Dothiepin	125
Doxepin	1000
Imipramine	850
Norclomipramine	50,000
Nordoxepin	1000
Nortriptyline	1000
Perphenazine	40000
Promazine	10000
Protryptiline	400
Trimipramine	1500
<b>AMP</b>	
D-Amphetamine	1,000
D,L-Amphetamine	1,500
L-Amphetamine	60,000
Benzphetamine	>100,000
<b>Specificity Compound</b>	<b>Concentration (ng/mL)</b>

D-Methamphetamine	>100,000
p-OH-Methamphetamine	>100,000
Methylenedioxyamphetamine	700
Methylenedioxymethamphetamine	>100,000
β-Phenethylamine	60,000
L-Phenylpropanolamine	>100,000
Phentermine	350
Tryptamine	50,000
Tyramine	70,000
3-OH-Tyramine	>100,000

#### REFERENCES:

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**ALTERNATIVE METHOD:**

List alternative method (or reference laboratory) to be used should the Status DS become unavailable.

Alternative Method:

Reference Laboratory

Name:  
Address:  
Address:  
Phone:  
Contact:

**CRITERIA FOR REFERRAL OF SPECIMENS:**

When referring specimens for outside testing, the following procedures are recommended:

1. Verify that the testing laboratory possesses a valid CLIA certification authorizing performance of the referred test.
2. Follow laboratory guidelines for specimen shipment.
3. Report results exactly as received (no alteration or revision either of results or interpretive information provided by the testing laboratory).
4. Permit direct test report from the testing laboratory to the authorized person or entity that ordered the test.
5. Retain or be able to produce an exact duplicate of each testing laboratory's report.
6. Provide the name and address where the test was performed and indicate this information on the test report.

**TECHNICAL ASSISTANCE:**

Technical assistance is available from the manufacturer of Status DS, LifeSign, LLC, Somerset, New Jersey, between the hours of 8:30 a.m. and 4:45 p.m. E.S.T.

1-800-526-2125