



## SURE-SCREEN<sup>®</sup>

SURE-SCREEN<sup>®</sup> is a rapid qualitative screening test system for drugs of abuse in human urine. **All SURE-SCREEN products are covered by this insert. Refer to product labeling for the actual drugs assayed by the test system configuration.**

The Lateral Flow (LatFlo<sup>®</sup>) Adulterant Strip (LFAS) is a rapid qualitative screening assay for the detection of Oxidants, Nitrites, the Determination of Specific Gravity, and pH Values in human urine. It is used to evaluate specimens for adulteration prior to Drugs of Abuse urine (DAU) testing. **The LFAS strip is only for Forensic/Toxicology use and not for in vitro diagnostic applications. The LFAS test strip is not contained in every SURE-SCREEN product.**

### 1. INTENDED USE

The SURE-SCREEN Drugs of Abuse Test System uses immunochromatographic test strips for the rapid, qualitative detection of one or more of the following: Amphetamine, Benzodiazepines, Cocaine, Methamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine and THC (Cannabinoids) in human urine. It is intended for prescription point-of-care use including workplace settings, criminal justice or forensic settings, drug rehabilitation clinics, physician offices and laboratory settings. SURE-SCREEN is not for over-the-counter sale.

Operators that may use this device are defined as individuals with at least a high school education, with no formal laboratory testing education or laboratory experience, and who have some experience running other tests similar to SURE-SCREEN. Additionally, individuals are to satisfy the following training and certification guidelines:

(1) Training should be conducted by a qualified professional and include a demonstration of the SURE-SCREEN test system and (2) the use of quality assurance samples for monitoring and confirming the performance of the test system. Trainers should observe and confirm that the operator (3) uses proper technique when running a test sample and quality assurance samples, (4) has a basic understanding of test results, including the potential for false positive and false negative results, (5) knows how to prepare a sample for shipment to the laboratory for confirmation testing, (6) has reviewed the information contained in the MEDTOX SURE-SCREEN Training and Certification Program (available at [www.medtox.com](http://www.medtox.com)) and that the operator (7) minimally achieves a score of 80% on the written exam provided by MEDTOX.

Operators achieving a score of 80% will be provided with a certificate of training participation. Quality assurance samples appropriate for training are available from MEDTOX Laboratories Inc. Additionally, MEDTOX Technical Support will provide access to assistance from individuals who are experienced in the interpretation of drug testing results.

SURE-SCREEN detects drug classes at the following cutoff concentrations:

AMP	Amphetamine (d-Amphetamine)	300 ng/mL
BZO	Benzodiazepines (Nordiazepam)	200 ng/mL
COC	Cocaine (Benzoylecgonine)	100 ng/mL
MAMP	Methamphetamine (d-Methamphetamine)	1000 ng/mL
MTD	Methadone (Methadone)	200 ng/mL
OPI	Opiates (Morphine)	100 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine (Phencyclidine)	25 ng/mL
THC	Cannabinoids (11-nor-9-carboxy- $\Delta^9$ -THC)	40 ng/mL

Many of the cutoff concentrations for these tests are below those recommended by SAMHSA. Additionally, many of these tests are positive at levels significantly below the claimed cutoff concentration. The rate of false positive results with tests having sensitivities this low has not been studied. However, the rate of false positives generally increases as the cutoff concentration of the test is lowered. See the Precision/Sensitivity section for more information.

The SURE-SCREEN drugs of abuse test system provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result.

It is the responsibility of those organizations required to follow Department of Transportation (DOT) or Substance Abuse Mental Health Services Administration (SAMHSA) Workplace Drug Testing Guidelines to determine that use of this product satisfies the criteria for workplace testing established under DOT and SAMHSA authority.

### 2. SUMMARY AND EXPLANATION OF THE TEST

The qualitative SURE-SCREEN Drugs of Abuse Test System utilizes a solid phase immunoassay technology to provide a very rapid test requiring no instrumentation. This test may be used to screen human urine samples for one or more of the following drug classes prior to confirmatory testing:

Amphetamines (AMP) are central nervous system stimulants. This group of compounds includes amphetamine, methamphetamine, and related designer drugs MDMA (Ecstasy).

Benzodiazepines (BZO), a group of structurally related central nervous system depressants, are primarily used to reduce anxiety and induce sleep.

Cocaine (COC) is a central nervous system stimulant. Its primary metabolite is benzoylecgonine.

Methamphetamine (MAMP) is a central nervous system stimulant (see Amphetamine).

Methadone (MTD) is a synthetic opioid used clinically as a maintenance drug for opiate abusers and for pain management.

Opiates (OPI) are a class of natural and semi-synthetic drugs that include morphine, codeine and heroin.

Oxycodone (OXY) (Oxycontin<sup>®</sup>, Percodan, Percocet) is a semi synthetic narcotic analgesic that is prescribed for moderately severe pain. It is available in both standard and sustained release oral formulations. Oxycodone is metabolized to Oxymorphone and Noroxycodone.

Phencyclidine (PCP) is a hallucinogenic drug.

Marijuana (THC) is a hallucinogenic agent derived from the hemp plant. Marijuana contains a number of active ingredients collectively known as Cannabinoids.

Many factors influence the length of time required for drugs to be metabolized and excreted in the urine. A variety of factors influence the time period during which drugs are detected; the rate of urine production, the volume of fluid consumption, the amount of drug taken, the urine pH, and the length of time over which drug was consumed. Drinking large volumes of liquid or using diuretics to increase urine volume lowers the drug concentration and decreases the detection period. Although the detection period for these drugs varies widely depending upon the compound taken, dose and route of administration and individual rates of metabolism, some general times have been established and are listed below.<sup>1,4, 6,8</sup>

<u>Drug</u>	<u>Detection Period</u>	<u>Drug</u>	<u>Detection Period</u>
Amphetamine		Opiates	
Acid Conditions	1-3 days	Heroin	1 day
Alkaline Condition	3-10 days	Morphine	1-3 days
		Codeine	1-3 days
Benzodiazepines	1-12 days	Oxycodone	1-3 days
Cocaine Metabolite	1-3 up t 5 days 1-3 days typical	PCP	
		Single Use	1-8 days
Methadone	1-3 days	Chronic Use	Up to 4 weeks
Methamphetamine		THC	
Acid Conditions	1-3 days	Single Use	1-3 days
Alkaline Conditions	3-10 days	Chronic Use	Less than 30 days typical

The LFAS is a lateral flow strip with impregnated reagent test pads that detect specific analytes in human urine. The specific analytes detected are Oxidants and Nitrites. The strip also approximates specific gravity and pH values. The temperature strips on the cup may be used to detect potential adulteration of the sample. Urine samples with “abnormal values” should be submitted to a reference laboratory for additional testing.

Oxidants The detection is based on the oxidative activity of compounds (e.g. chromate salts and/or bleach) that catalyze the oxidation of an indicator by an organic hydroperoxide producing a blue/orange color. The color intensity is directly proportional to the concentration of oxidants present in the sample and is observed visually and compared to the color comparator chart to obtain a result.

Nitrites The test is based on the principles of the Griess reaction for the detection of Nitrites. The test paper contains an amine and a coupling component. A red/orange colored azo compound is obtained by diazotization and subsequent coupling. The color intensity is directly proportional to the concentration of nitrites present in the sample and is observed visually and compared to the color comparator chart to obtain a result.

pH The test paper contains indicators that change colors between pH 2 and pH 11. The color scale gives an approximate indication for pH values between those levels.

Specific Gravity The test paper reacts with ions in urine to indicate concentrations from 1.000 to 1.020. The color changes range from dark green with low ionic concentrations through green to yellow/orange in urines with high ionic concentrations. The color is observed visually and compared to the color comparator chart to obtain an approximate result.

### 3. PRINCIPLES OF THE PROCEDURE

The SURE-SCREEN Drugs of Abuse Test System contains a device with rapid, competitive, membrane-based immunochromatographic test strips, a cup and a lid. A single urine sample can be evaluated for the presence of each of the specified classes of drugs in a single device. Each test strip contains antibody colloidal gold, a drug conjugate and a control line.

**ANTIBODY-COLLOIDAL GOLD** -- Mouse monoclonal antibodies were developed specifically targeted to the drugs listed in the Intended Use section. Each antibody only binds drugs from the tested drug classes. Antibody-colloidal gold solutions were prepared by absorbing each of the individual monoclonal antibodies to colloidal gold. The colloidal gold solutions were applied to the sample well pads on the test strip.

**DRUG-CONJUGATES** -- Drug from each tested class was individually conjugated to protein and immobilized as a line on a membrane at the location labeled “T” on the device.

**CONTROL LINE** -- Each test strip has anti-mouse immunoglobulin antibodies immobilized as a line on the membrane at the location labeled “C” on the device. The anti-mouse immunoglobulin antibodies bind the mouse antibodies coated on the colloidal gold.

Drugs in the urine and the drugs conjugated to the protein compete to bind to the antibody-colloidal gold. When the test system is tipped over, urine flows into the sample well of the device, the dried antibody-colloidal gold on the sample pad dissolves and the urine wicks up the white test strips carrying the red antibody-colloidal gold with it.

#### Negative Samples

When no drug(s) is present in the urine sample, the red antibody-colloidal gold migrates up the test strip and binds to the drug conjugate immobilized on the membrane. The binding of the antibody-colloidal gold to the drug conjugate generates an easily visible reddish-purple line at the “T” location on the device. Strips with two tests will be labeled with two colors and are on left-hand side of device. The top color will indicate the T1 test with T1= drug test name. The bottom color will indicate the T2 test with T2= drug test name. Strips with only one color will have test results appear at the T1 position. Negative results can be reported as soon as a line is visible.

#### Non-Negative Samples

When a drug is present in the sample the antibody-colloidal gold binds the drug before it migrates up the test strip. However, when the antibody-colloidal gold binds the drug in the urine, the antibody-colloidal gold cannot bind to the drug conjugate immobilized on the test strip. When the drug concentration is at or above the cutoff concentration, the majority of the antibody colloidal gold is bound to the drug from the urine. Therefore, as drug bound antibody-colloidal gold migrates up the test strip, it is unable to bind to the drug conjugate immobilized on the membrane. Therefore no line is generated at the “T” location on the device for a non-negative sample. Read non-negative results at 5 minutes.

#### Control Line

Each test strip has an internal procedural control. A line must form at the control “C” location on the device to indicate that the reagents are migrating properly. If a control line does not form, the test is considered invalid. A control line forms when the antibody-colloidal gold binds to the anti-mouse immunoglobulin antibody immobilized on the membrane as a line at the “C” location on the device.

#### **4. MATERIALS PROVIDED/STORAGE CONDITIONS**

Each SURE-SCREEN Drugs of Abuse Test System/Kit contains all the reagents necessary to test one urine sample for one or more drugs simultaneously. SURE-SCREEN devices are available in Cup or Dip format as described below.

##### **Kit Contents – Cup Test System**

The SURE-SCREEN Drugs of Abuse Cup Test System kit contains twenty-five (25) test system bags and one reference guide.

##### **Cup Test System Bag Contents**

1. One (1) test device in a foil package.
  1. The test strips each contain a membrane coated with drug conjugate and a pad coated with antibody dye complexes in a protein matrix.
  2. The test device may contain a membrane strip laminated with Adulterant test pads for testing the presence of Oxidants and Nitrites, as well as determining approximate values of Specific Gravity and pH in human urine. **The LFAS test strip is not contained in every SURE-SCREEN product.**
2. One (1) cup with temperature strip attached.
3. One (1) lid.
4. One (1) security seal.
5. One (1) Color Comparator Chart (products with LFAS test strip only).

##### **Kit Contents – Dip Device**

The SURE-SCREEN Drugs of Abuse Dip Test Kit contains one hundred (100) test devices in foil packages (see Test System Bag contents for details of test strips), and one reference guide.

A urine collection container is not provided with the dip device. Specimen containers, disposable gloves and urine temperature strips are available from MEDTOX Diagnostics, Inc.

##### **Kit Contents – Sample Pack**

The SURE-SCREEN Drugs of Abuse sample kit contains five (5) cup test system bags (see above for cup test system bag contents), five (5) dip test devices in foil packages, and two (2) reference guides.

##### **Storage Conditions**

The kit, in its original packaging, should be stored at 2-25°C (36-77°F) until the expiration date on the label.

#### **5. PRECAUTIONS**

1. Urine specimens and all materials coming in contact with them should be handled and disposed of as if infectious and capable of transmitting infection. Never pipette by mouth and avoid contact with broken skin.
2. The device should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, do not use the test.
3. Do not store the test kit at temperatures above 25°C (77°F).
4. If devices have been stored refrigerated, bring to ambient temperature (18-25°C/ 64-77°F) prior to opening foil pouch.
5. Do not use tests after the expiration date printed on the package label.
6. The drug screen portion of the device is for in vitro diagnostic use only. The LFAS strip is for Forensic/Toxicology use only.

#### **6. SAMPLE COLLECTION AND PREPARATION**

If using a Cup Test System, the urine sample should be collected in the provided cup. The urine volume should be between the minimum and maximum volume lines. If using a Dip Device, collect the urine sample in a clean dry container. Collection of 45 mL of urine is more than sufficient for testing. No preservatives should be added. Urine may be tested immediately following collection. If it is necessary to store the urine, store under refrigeration for no more than one day. Urine may be frozen for longer storage. Stored urine must be brought to ambient temperature (18 to 25°C/64 to 77°F) and mixed well to assure a homogeneous sample prior to testing.

#### **7. TEST PROCEDURE**

##### **Cup Test System**

1. Fill cup between the minimum and maximum volume lines.
2. Screw lid clockwise onto the cup until tight.
3. Open pouch and label the device with the patient or sample identification.
4. Secure device snugly to lid as noted on the lid icon.
5. Tip the cup on its side as shown below to start flow (if less than 45 ml of urine, tilt the cup forward to begin flow).
6. Allow the test system to sit for 5 minutes.
7. Turn the test system upright and read the results. Negative results can be read as soon as a line is visible, non-negatives at 5 minutes.

##### **Dip Device**

1. Open one pouch for each sample to be tested. Tear pouch carefully using the notch at the top above the arrows.
2. Open the flap and fold back to expose the fiber pads at ends of test strips.
3. Dip the ends of the test strips into the urine sample no deeper than the dotted line on the colored strips. Hold the ends of the test strips in the sample until the reddish-purple solution begins to run up all of the strips.
4. Remove the device from sample and lay flat.
5. Read the results at 5 minutes after laying flat.
6. Fold at lower perforation to cover the wet ends of test strips. The device folder may be used to protect the strips to view the result. Write patient or sample identification information in the ID box.

**NOTE:** Oxycodone should be read at 5 minutes. The test result for Oxycodone after 5 minutes may not be consistent with the original reading. For all other tests, read results at 5 minutes or within 15 minutes of the sample application. The test result after 15 minutes may not be consistent with the original reading.

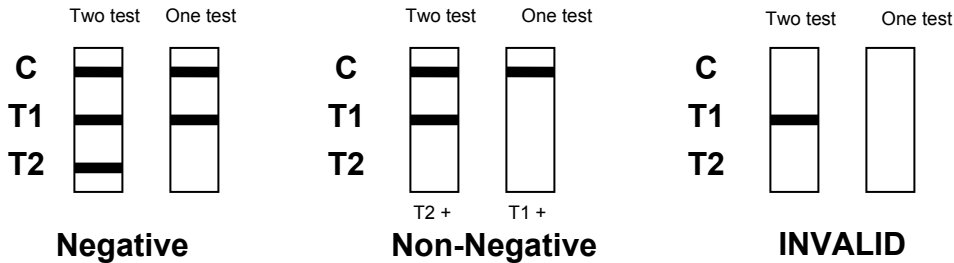
## 8. READING THE TEST RESULTS

**Negative:** The appearance of a reddish purple line at both the control area (C) and appropriate test area (T) indicates a negative test result. The color intensities of the control lines (C) and test lines (T) may not be equal and may vary from test to test. The test line and control line positions may vary slightly from test strip to test strip. Any line of reddish-purple color, even of faint intensity, indicates a negative test result.

**Non-Negative:** The appearance of a control line and the absence of a test line indicate a preliminary positive test result for that drug.

**Invalid:** The control line must be present for the test to be valid. The absence of a control line indicates the test is invalid. The urine sample should be retested on a new device.

Examples of Negative, Non-Negative and Invalid results:



## 9. INTERPRETATION OF TEST RESULTS

A NEGATIVE test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level.

A NON-NEGATIVE test result for a specific drug indicates that the sample may contain drug/drug metabolite near or above the cutoff level. It does not indicate the level of intoxication or the specific concentration of drug in the urine sample. Non-negative samples or those with abnormal LFAS tests should be sent to a reference laboratory for more definitive testing.

### Understanding the Test Results:

A non-negative test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

*In general, the Substance Abuse and Mental Health Services Administration (SAMHSA) reports the accuracy of drug tests as the following for Preliminary Positive Tests<sup>4</sup>:*

60 out of 100 times a "preliminary positive" result from an opiate test is a "false preliminary positive" result. This means that the result of the first test was "preliminary positive" even though the person did <u>not</u> take an illegal drug.
50 out of 100 times a "preliminary positive" test result from an amphetamine or methamphetamine test is a "false preliminary positive" result.
50 out of 100 times a "preliminary positive" result from a PCP (phencyclidine) test is a "false preliminary positive" result.
10 out of 100 times a "preliminary positive" result from a marijuana test is a "false preliminary positive" result.
2 out of 100 times a "preliminary positive" result from a cocaine test is a "false preliminary positive" result.

<sup>4</sup> Data was generated from laboratory tests that have the following cutoff concentrations: Marijuana, 50 ng/mL; Cocaine, 300 ng/mL; Phencyclidine, 25 ng/mL; Opiates, 2000 ng/mL; Amphetamine, 1000 ng/mL.

Many of the cutoff concentrations for SURE-SCREEN are below those recommended by SAMHSA. Additionally, many of these tests are positive at levels significantly below the claimed cutoff concentration. The rate of false positive results with tests having sensitivities this low has not been studied. However, the rate of false positives generally increases as the cutoff concentration of the test is lowered. See the Precision/Sensitivity section for more information.

*For Negative Tests:* A negative result does not always mean a person did not take illegal drugs. For example, you will get a negative result if the test is for cocaine when the person tested has only smoked marijuana. There are a number of reasons why you can get a "false negative" test result. A false negative test result means the test result is negative when the person has actually taken the drug that this test is designed to detect. This might happen under the following circumstances:

1. The drug may not have been in the sample at the time the sample was collected. It takes a while after taking a drug for it to appear in a specimen, and it only stays in the specimen for a limited amount of time. If the sample was taken too early or too late you can get a "false negative" result.
2. The person, knowing that they were going to be tested, added something to the specimen to keep it from reacting with the test chemicals. This could cause a false negative result. There are products sold for this purpose.
3. The drug may be in the specimen because the person took the drug, but it is there at such a low concentration that the drug cannot be detected by the test.
4. The test may not be working properly. There are a number of things that could be wrong with any testing product. It might have been damaged during shipment or kept at the wrong temperature, either before or after you received it. Storing a product at temperatures that are too high or too low can damage the chemicals in the test.

If you get a negative test result but you still suspect someone is taking drugs you should test again at another time, or test for different drugs.

## 10. QUALITY CONTROL

An internal procedural control is included on each test strip. A line must form at the control (C) position on the test strip to indicate that adequate sample volume has been added, the reagents migrated properly, and the test strip is intact. If a control line does not form, the test is considered invalid. The control line consists of immobilized anti-mouse antibody that reacts with the antibody-colloidal gold as it passes this region of the membrane. Formation of a visible line verifies the control line antibody antigen reaction occurred. A visible control line should always be present regardless of whether drug is absent or present in the sample. Minimally, a QC program includes external negative and positive control material used to monitor the performance of each new lot of product, each new shipment of product and may be used to assess the competency of new operators.

For additional information concerning QC, forensic or workplace testing requirements, contact the appropriate regulatory authority. Users should follow federal, state, and local QC requirements.

## 11. LIMITATIONS OF THE PROCEDURE

1. The SURE-SCREEN Drugs of Abuse Test System is only for use with unadulterated human urine samples.
2. There is a possibility that other substances and/or factors, e.g. technical or procedural errors, may interfere with the test and cause false results.

### **LFAS Strip**

The purpose of the adulteration strip is to screen for abnormal conditions in human urine, such as dilution or the addition of drug-test interfering substances. Occasionally medications may discolor the urine making it difficult to read the result.

#### **Oxidant**

Nitrites acting as oxidizing agents will produce a blue/green color change on the Oxidant Pad.

#### **Nitrite**

Abnormal results can be caused by the presence of diagnostic or therapeutic dyes in the urine. Very high concentrations of oxidant such as 80% bleach will produce a brown color change on the Nitrite pad.

## 12. EXPECTED VALUES

### **SURE-SCREEN TEST SYSTEM:**

SURE-SCREEN Drugs of Abuse Test System qualitatively detects amphetamine, benzodiazepines, cocaine, methadone, methamphetamine, opiates, oxycodone, phencyclidine and THC (Cannabinoids) and/or their metabolites in human urine at or above their specified cutoff level. Illicit drugs should never be found in urine, and legal drugs (such as amphetamine, methamphetamine, benzodiazepine, opiates, oxycodone, or methadone) may appear in the urine for legitimate reasons. Confirmatory test results should be reviewed by a Medical Review Officer for interpretation.

## 13. PERFORMANCE CHARACTERISTICS

### **13A. Sensitivity, Accuracy, and Precision**

#### **Accuracy**

The accuracy was evaluated by assaying a panel of blind coded clinical urine samples containing varying concentrations of drugs and comparing to GC/MS or LC/MS/MS results. The samples were obtained from MEDTOX Laboratories. Samples were screened at traditional laboratory cutoff concentrations by a commercial immunoassay system. Samples with negative results by both the commercial immunoassay system and SURE-SCREEN were not confirmed by GC/MS or LC/MS/MS. Samples with positive results by either the commercial immunoassay system or SURE-SCREEN were confirmed by GC/MS or LC/MS/MS. Most samples were unaltered clinical samples. In order to have samples with concentrations close to the cutoff, some samples were diluted with negative urine. The five minute results are shown in the following tables. The testing was performed by MEDTOX personnel.

**ACCURACY COMPARED TO GC/MS OR LC/MS/MS  
(Amphetamine, Benzodiazepines, Cocaine, Methamphetamine, Methadone, Opiates, Phencyclidine and Cannabinoids (THC))**

<b>5 Minute</b>	Negative by immunoassay; if positive, no drug was detected above the limit of detection of the confirmatory method	Concentration range of up to 50% below the cutoff (ng/mL)	Concentration range between the -50% of the cutoff and the cutoff (ng/mL)	Concentration range between the cutoff and 50% above the cutoff (ng/mL)	Concentration range of greater than 50% above the cutoff (ng/mL)
<b>AMP</b>			180 – 255	334 – 402	474 – 11845
Positive	0	Not performed	4	4	32
Negative	55	Not performed	1	1	1
Samples are categorized according to d-amphetamine concentrations.					
<b>BZO</b>			113 - 151	220 - 281	428 - 12491
Positive	0	Not performed	4	5	33
Negative	54	Not performed	0	0	0
Nordiazepam, oxazepam, temazepam, alprazolam and $\alpha$ -hydroxy-alprazolam were added together to determine the total benzodiazepine concentration reported in the table. 6 samples were diluted with negative urine to obtain concentrations around the cutoff.					
<b>COC</b>			55 - 91	110 - 140	153 - 96924
Positive	0	Not performed	6	5	36
Negative	54	Not performed	0	0	0
Samples are categorized by benzoylecgonine concentrations (cocaine metabolite).					
<b>MTD</b>			112 - 114	249 - 283	307 - 9411
Positive	0	Not performed	2	6	44
Negative	98	Not performed	2	1	0
<b>OPI</b>			76 – 90	111 – 147	251 – 136360
Positive	0	Not performed	4	4	36
Negative	54	Not performed	0	0	0
Morphine, codeine, hydrocodone and hydromorphone were added together to determine the total opiate concentrations reported in this table.					
<b>PCP</b>			13 - 22	27 - 35	39 - 5439
Positive	0	Not performed	2	5	33
Negative	55	Not performed	3	0	0
<b>THC</b>		3	21 - 37	42 - 54	62 - 761
Positive	0	0	5	8	34
Negative	55	1	1	0	0
11-nor-9-carboxy- $\Delta^9$ -THC concentrations are reported in this table					
GC/MS Methamphetamine (limit of quantitation 50 ng/mL)					
		Positive	Negative	Total	
<b>MAMP</b>	Positive	56	0	56	
<b>(1000 ng/mL</b>	Negative	2	56	58	
<b>Cut-off)</b>	Total	58	56	114	
Overall agreement >98% (112/114). Samples having discrepant results were analyzed by GC/MS. The false negative samples contained methamphetamine at 1056 ng/mL and at 1136 ng/mL.					

**ACCURACY AND RELIABILITY IN A POC SETTING  
(Amphetamine, Benzodiazepines, Cocaine, Methadone, Opiates, Phencyclidine and Cannabinoids (THC))**

The accuracy and reliability of SURE-SCREEN tests was assessed by comparing the results generated by 44 POC operators at 13 POC sites and GC/MS or LC/MS/MS. The operators were provided with the package insert instructions to run the test system. Operators that used this device generally had at least a high school education, with no formal laboratory testing education or laboratory experience, and who had some experience running other similar tests to SURE-SCREEN. 93% of the participants had no laboratory testing education or laboratory experience; 88% used a point-of-care testing device before. 1000 samples were coded and evaluated in a blind study. The 1000 samples were divided into batches and distributed to the participants. The unaltered clinical samples were obtained from MEDTOX Laboratories Inc, a SAMHSA certified / CLIA-CAP Accredited Laboratory. Positive and negative samples were identified by initially screening at traditional cutoff levels with a commercial immunoassay system. Samples with negative results by both the commercial immunoassay system and SURE-SCREEN were not confirmed by GC/MS or LC/MS/MS. Samples with positive results by either the commercial immunoassay system or SURE-SCREEN were confirmed by GC/MS or LC/MS/MS.

The number of POC facilities and operators					
Facility Type	Criminal Justice	Treatment Center	Clinic/Physician Office Laboratory	DAU Collection Site	Total
Sites	2	2	7	2	13
Operators	18	3	11	12	44
Samples	375	75	250	300	1000
ACCURACY COMPARED TO GC/MS OR LC/MS/MS (Amphetamine, Benzodiazepines, Cocaine, Methadone, Opiates, Phencyclidine and Cannabinoids (THC))					
POC Users	Negative by immunoassay; if positive, no drug was detected above the limit of detection of the confirmatory method	Concentration range of up to 50% below the cutoff (ng/mL)	Concentration range between the -50% of the cutoff and the cutoff (ng/mL)	Concentration range between the cutoff and 50% above the cutoff (ng/mL)	Concentration range of greater than 50% above the cutoff (ng/mL)
<b>AMP</b>		119	217-257	306	510-9489
Positive	6	0	4	1	21
Negative	967	1	0	0	0
Samples are categorized according to d-amphetamine concentrations.					
<b>BZO</b>		34-38	113-174	245-268	315-32454
Positive	0	1	5	2	17
Negative	971	1	2	0	0
Nordiazepam, oxazepam, temazepam, alprazolam and $\alpha$ -hydroxy-alprazolam were added together to determine the total benzodiazepine concentration reported in the table.					
<b>COC</b>		16-48	57-96	113-133	200-39644
Positive	1	1	4	5	28
Negative	959	2	0	0	0
Samples are categorized by benzoylcegonine concentrations (cocaine metabolite).					
<b>MTD</b>				207	335-8377
Positive	0	Not performed	Not performed	1	6
Negative	993	Not performed	Not performed	0	0
<b>OPI</b>		28	60	124-143	241-11724
Positive	8	1	1	2	25
Negative	963	0	0	0	0
Morphine, codeine, hydrocodone and hydromorphone were added together to determine the total opiate concentrations reported in this table.					
<b>PCP</b>					236-373
Positive	0	Not performed	Not performed	Not performed	4
Negative	996	Not performed	Not performed	Not performed	0
<b>THC</b>		5-17	23-26	47-59	60-481
Positive	8	4	3	6	30
Negative	946	3	0	0	0
11-nor-9-carboxy- $\Delta^9$ -THC concentrations are reported in this table.					

**Sensitivity/Precision**

Performance around the specific cutoff for each drug was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different intervals by 3 in-house operators. Drug-free urine was also tested on each interval. The results were interpreted at five minutes.

<b>Amphetamine (d-Amphetamine) Cutoff = 300 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
0	540	0	540
75	45	0	45
150	45	13	32
225	45	38	7
<b>300</b>	45	44	1
375	45	44	1
450	45	44	1

<b>Benzodiazepines (Nordiazepam) Cutoff = 200 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	540	0	540
50	45	30	15
100	45	40	5
150	45	45	0
<b>200</b>	45	45	0
250	45	44	1
300	45	45	0

<b>Cocaine (Benzoyllecgonine) Cutoff = 100 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	540	0	540
25	45	0	45
50	45	19	26
75	45	25	20
<b>100</b>	45	35	10
125	45	44	1
150	45	41	4

<b>Methamphetamine (d-Methamphetamine) Cutoff = 1000 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
0	30	0	30
100	30	0	30
250	30	0	30
500	30	26	4
750	30	27	3
<b>1000</b>	30	28	2
1250	30	29	1
1500	30	30	0
2000	30	30	0

<b>Methadone (Methadone) Cutoff = 200 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	405	0	405
50	45	4	41
100	45	37	8
150	45	44	1
<b>200</b>	45	45	0
250	45	44	1
300	45	45	0

<b>Opiate (Morphine) Cutoff = 100 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	540	0	540
25	45	20	25
50	45	38	7
75	45	44	1
<b>100</b>	45	45	0
125	45	44	1
150	45	43	2

<b>Phencyclidine (Phencyclidine) Cutoff = 25 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	540	0	540
6.25	45	1	44
12.50	45	0	45
18.75	45	17	28
<b>25.00</b>	45	43	2
31.25	45	43	2
37.50	45	44	1

<b>Cannabinoids (11-nor-9-carboxy-<math>\Delta^8</math>-THC) Cutoff = 40 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	105	0	105
10	45	0	45
20	45	0	45
30	45	1	44
<b>40</b>	45	45	0
50	45	40	5
60	45	45	0

Precision POC Operators:

Performance around the cutoff for each drug was evaluated by testing drug-free negative urine that was spiked with drug at the various concentrations listed in the following tables. 3 POC operators tested 15 replicates of each sample. These 3 operators had at least a high school education, with no formal laboratory testing education or laboratory experience, and had some experience running other tests similar to SURE-SCREEN. The results are summarized in the table below:

<b>Amphetamine (d-Amphetamine) Cutoff = 300 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	135	0	135
75	45	4	41
150	45	35	10
300	45	45	0
375	45	45	0

<b>Benzodiazepines (Nordiazepam) Cutoff = 200 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	135	0	135
50	45	1	44
100	45	4	41
200	45	9	36
250	45	45	0

<b>Cocaine (Benzoyllecgonine) Cutoff = 100 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	135	0	135
25	45	0	45
50	45	6	39
100	45	26	19
125	45	45	0

<b>Methadone (Methadone) Cutoff = 200 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	135	0	135
50	45	4	41
100	45	22	23
200	45	25	20
250	45	45	0

<b>Opiate (Morphine) Cutoff = 100 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	135	0	135
25	45	0	45
50	45	0	45
100	45	7	38
125	45	43	2

<b>Phencyclidine (Phencyclidine) Cutoff = 25 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	135	0	135
6.25	45	1	44
12.5	45	34	11
25.0	45	44	1
31.25	45	45	0

<b>Cannabinoids (11-nor-9-carboxy-<math>\Delta^9</math>-THC) Cutoff = 40 ng/mL</b>			
<u>Conc. (ng/mL)</u>	<u>Number Tested</u>	<u>Positive</u>	<u>Negative</u>
Negative	135	0	135
10	45	2	43
20	45	14	31
40	45	25	20
50	45	45	0

**Accuracy in a Point of Care setting (Oxycodone)**

The accuracy was evaluated by assaying a panel of blind coded clinical urine samples containing varying concentrations of drugs and comparing to GC/MS results. The samples were obtained from MEDTOX Laboratories. Samples that screened negative by the predicate device were not confirmed by GC/MS. Positive samples were confirmed by GC/MS. The GC/MS determination included Oxycodone and oxymorphone and a weighted concentration using 100% cross-reactivity for Oxycodone and a 50% cross-reactivity for oxymorphone was calculated. Clinical urine samples containing Oxycodone and oxymorphone at higher concentrations were diluted with negative urine to obtain the desired number of samples with concentrations below and above the cutoff. The testing was performed by nine point of care personnel at three sites.

**MEDTOX® OXYCODONE Results vs stratified GC/MS Values**

MEDTOX® OXYCODONE Results	Negative by Immunoassay (Predicate Device)	Concentration up to 50% below the cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	2	2	6	37
Negative	103	5	4	1	1

GC/MS values used to categorize samples in this table are determined by adding together the concentration of Oxycodone plus 50% of the concentration of oxymorphone, based on the MEDTOX® OXYCODONE cross-reactivity studies.

% Agreement among positives is 96%  
 % Agreement among negatives is 97%

A second, in-house accuracy study was done using many of the same samples as in the POC study above. Results between the two studies were similar.

**Sensitivity/Precision at One Location (Oxycodone)**

Performance around the specific cutoff for Oxycodone was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 6 different intervals by 3 in-house operators. Drug free urine was also tested on each interval. The results were interpreted at five minutes and are summarized below:

**MEDTOX® OXYCODONE Precision Study Results**

Concentration of sample (ng/mL)	Number of determinations	Results #Neg / #Pos
0	54	54 / 0
25	54	54 / 0
50	54	50 / 4
75	54	14 / 40
100	54	4 / 50
125	54	1 / 53
150	54	0 / 54

**Sensitivity/Precision at Point of Care Sites (Oxycodone)**

Performance around the cutoff was evaluated by testing standard drug solutions diluted in drug-free urine at the various concentrations listed in the following table. 9 POC users at 3 different sites each tested 5 replicates of the 6 levels. The results obtained from the 3 sites, (Site 1, Site 2, Site 3) are listed below:

**MEDTOX® OXYCODONE Precision Study Results at Point of Care Sites**

Concentration of sample (ng/mL)	Number of determinations			Results #Neg / #Pos		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
0	15	15	15	15 / 0	15 / 0	15 / 0
25	15	15	15	15 / 0	15 / 0	15 / 0
50	15	15	15	13 / 2	15 / 0	14 / 1
100	15	15	15	0 / 15	3 / 12	3 / 12
125	15	15	15	0 / 15	2 / 13	1 / 14
150	15	15	15	0 / 15	0 / 15	0 / 15

**13B. Non Crossreactive Endogenous Compounds**

Listed compounds were initially dissolved in appropriate solvents and then added to drug-free urine for evaluation with all nine SURE-SCREEN tests. Most of the compounds were evaluated for reactivity with the SURE-SCREEN tests at 100 µg/mL (albumin was evaluated at 20 mg/mL and bilirubin was evaluated at 200 µg/mL). Samples were evaluated in triplicate by in-house operators. The listed compounds gave negative results with all nine of the SURE-SCREEN tests.

Acetaldehyde	Creatinine	Hemoglobin, Human
Acetone	Epinephrine	Sodium Chloride
Albumin, Human	β-Estradiol	Tetrahydrocortisone
Bilirubin	Estril	d,1-Thyroxine
Cholesterol	Glucose Std. Solution	Uric Acid

**13C. Unrelated Compounds, Prescription and Over-the-Counter Medications**

Listed compounds were initially dissolved in appropriate solvents and then added to drug-free urine for evaluation with all nine SURE-SCREEN tests. Most of the compounds listed in Section 13C were evaluated for reactivity with the SURE-SCREEN tests at 100 µg/mL. (Alprazolam, 1-hydroxy; Buprenorphine, Fentanyl, Lorazepam glucuronide, 11-Nor-9-carboxy-Δ<sup>8</sup>-THC, Olanzapine, and Oxazepam glucuronide were evaluated at 10µg/mL. 11-Nor-9-carboxy-Δ<sup>8</sup>-THC was evaluated

at 5 µg/mL). When a drug name is followed by an abbreviation such as "AMP", "BZO", etc, check the Related and Reactive Compounds listing in Section 13D for the reactivity of the drug with the appropriate test (AMP, BZO, etc). Samples were evaluated in triplicate by in-house operators. Unless noted in the Related and Reactive Compounds Section, the listed compounds gave negative results with all nine of the SURE-SCREEN tests.

Acetaminophen (N-Acetylprocainamide)	Acetaminophen	Acetylsalicylic Acid	Allobarbitol	Alprazolam- <b>BZO</b>	Alprazolam, 1-Hydroxy- <b>BZO</b>
p-Aminobenzoic Acid	7-Amino-clonazepam- <b>BZO</b>	7-Amino-flunitrazepam- <b>BZO</b>	Aminoglutethimide	l-Aminopyrine (4-(dimethylamino) antipyrine)	Amitriptyline
Amobarbital	Amoxapine	Amoxicillin	d-Amphetamine- <b>AMP</b> , <b>MAMP</b>	l- Amphetamine- <b>AMP</b> , <b>MAMP</b>	Ampicillin
Aprobarbital	Apomorphine- <b>OPI</b> , <b>OXY</b>	l-Ascorbic Acid	Aspartame	Atenolol	Atropine Sulfate
Barbital	Barbituric Acid	Benzilic Acid	Benzoic Acid	Benzocaine (ethyl - 4-aminobenzoate)	Benzoyllecgonine- <b>COC</b>
Benzphetamine	Benztropine	Brompheniramine	Buprenorphine	Bupropion	Butabarbital
Butalbital	Caffeine	Cannabidiol- <b>THC</b>	Cannabinol- <b>THC</b>	Captopril	Carbamazepine
Carbamazepine-10,11 epoxide	Carisoprodol (Meprobamate)	Cephalexin	Chloral Hydrate	Chloramphenicol	Chlordiazepoxide- <b>BZO</b>
Chloroquine	Chlorothiazide	Chlorpheniramine	Chlorpromazine	Chlorprothixene	Clobazam- <b>BZO</b>
Clomipramine	Clonazepam- <b>BZO</b>	Clonidine	Clorazepate- <b>BZO</b>	Clozapine	Cocaine- <b>COC</b>
Codeine- <b>OPI</b> , <b>OXY</b>	Cortisone	Cotinine	Cyclobenzaprine	Cyclopentobarbital	Deoxycorticosterone
Desalkylflurazepam- <b>BZO</b>	Desipramine	Desmethylchlordiazepoxide (Norchlordiazepoxide)- <b>BZO</b>	Desmethylflunitrazepam- <b>BZO</b>	Desmethylvenlafaxine	Dexamethasone
Dextromethorphan	Diacetylmorphine- <b>OPI</b> , <b>OXY</b>	Diazepam- <b>BZO</b>	Diclofenac	Diethylpropion	Diflunisal
Digoxin	Dihydrocodeine- <b>OPI</b>	Dimenhydrinate (Dramamine)	1,3-Dimethylbarbituric acid	Diphenhydramine	Domperidone
Dopamine	Doxepin	Doxylamine	Ecgonine- <b>COC</b>	Ecgonine Methyl Ester- <b>COC</b>	EDDP (Primary metabolite of methadone)- <b>MTD</b>
Efavirenz (Sustiva)	EMDP (Secondary metabolite of methadone)- <b>MTD</b>	Ephedrine- <b>AMP</b> , <b>MAMP</b>	Equilin	Erythromycin	Estrone
Ethanol	Ethylmorphine- <b>OPI</b> , <b>OXY</b>	Fenfluramine- <b>MAMP</b>	Fenpropofen	Fentanyl (Synthetic opiate)	Flunitrazepam- <b>BZO</b>
Fluoxetine (Prozac)	Flurazepam- <b>BZO</b>	Furosemide	Fluvoxamine	Gentisic Acid (2,5-Dihydroxybenzoic acid)	Glutethimide
Guaiacol Glyceryl Ether	Haloperidol	Hexobarbital	Hippuric acid	Hydralazine	Hydrochlorothiazide
Hydrocodone- <b>OPI</b> , <b>OXY</b>	Hydrocortisone	Hydromorphone- <b>OPI</b> , <b>OXY</b>	Hydroxybupropion	Hydroxyhippuric acid	l-11-Hydroxy- $\Delta^9$ - <b>THC</b> - <b>THC</b>
p-Hydroxyphenobarbital	4-Hydroxyphenacyclidine- <b>PCP</b>	3-Hydroxytyramine	Hydroxyzine	Ibuprofen	Imipramine
Iproniazid	(R)-Isoproterenol	Isoxsuprine	Ketamine	Ketoprofen	Labetalol
Levorphanol- <b>OPI</b> , <b>OXY</b>	Lidocaine	Lithium carbonate	Loperamide	Lorazepam- <b>BZO</b>	Lorazepam glucuronide- <b>BZO</b>
Loxapine	Lysergic Acid	Lysergic Acid Diethylamide (LSD)	Maprotiline	MDA- <b>AMP</b> , <b>MAMP</b>	MDE (MDEA)- <b>AMP</b> , <b>MAMP</b>
MDMA- <b>AMP</b> , <b>MAMP</b>	Melanin	Meperidine	Mephobarbital	Mepivacaine	Mesoridazine
Methadone- <b>MTD</b>	d-Methamphetamine- <b>AMP</b> , <b>MAMP</b>	l-Methamphetamine- <b>AMP</b> , <b>MAMP</b>	Methaqualone	Methcathinone	Methocarbamol
Methoxyphenamine	Methylphenidate	Methylprylon	Metoprolol	Midazolam- <b>BZO</b>	Mirtazapine
6-Monoacetylmorphine- <b>OPI</b> , <b>OXY</b>	Morphine- <b>OPI</b> , <b>OXY</b>	Morphine 3- $\beta$ -D-Glucuronide- <b>OPI</b> , <b>OXY</b>	Morphine 6- $\beta$ -D-Glucuronide- <b>OPI</b> , <b>OXY</b>	Nalidixic Acid	Naltrexone- <b>OPI</b> , <b>OXY</b>
Nalorphine- <b>OPI</b> , <b>OXY</b>	Naloxone- <b>OPI</b> , <b>OXY</b>	Naproxen	Niacinamide	Nicotine	Nifedipine
Nitrazepam- <b>BZO</b>	Nitrofurantoin	Norclomipramine	Norcodeine- <b>OPI</b> , <b>OXY</b>	Nordiazepam-	Nordoxepin
Norethindrone	Norlysergic Acid	Normeperidine	Norpropoxyphene- <b>PPX</b>	l-Norpseudoephedrine	11-Nor-9-carboxy- $\Delta^9$ - <b>THC</b> - <b>THC</b>
11-Nor-9-carboxy- $\Delta^8$ - <b>THC</b> - <b>THC</b>	Nortriptyline	Noscapine	Nylidrin	Octopamine	Ofloxacin
Olanzapine (Zyprexa)-TCA positive-Anti-Psychotic	Omeprazole	Orphenadrine	Oxalic Acid	Oxaprosin	Oxazepam- <b>BZO</b>
Oxazepam glucuronide- <b>BZO</b>	Oxolinic Acid	Oxycodone- <b>OPI</b>	Oxymetazoline	Oxymorphone- <b>OPI</b> , <b>OXY</b>	Papaverine hydrochloride
Pentazocine	Pentobarbital	Perphenazine	Phenallymal (Alphenal)	Phenacetin (Acetophenetidin)	Phendimetrazine
Phenelzine	Phenethylamine- <b>AMP</b> , <b>MAMP</b>	Pheniramine	Phenmetrazine	Phenobarbital	Phenothiazine
Phenothiazine	Phentemine- <b>AMP</b> , <b>MDMA</b>	Phentoin (Diphenhydantoin)- <b>BAR</b>	Phenylbutazone	Phenylephrine	Phenylpropranolamine
Piroxicam	Prazosin	Prednisolone	Prednisone	Procaine	Procainamide
Prochlorperazine	Promazine	Promethazine	Propoxyphene	Propranolol	Protriptyline
Pseudoephedrine- <b>MAMP</b>	Pyrilamine	Quetiapine (Seroquel)-TCA positive-Anti-Psychotic	Quinidine	Ranitidine	Riboflavin

Rifampin	Salicylic Acid	Secobarbital	Selegiline (Deprenyl)	Serotonin (5-Hydroxytryptamine)	Sertraline (Zoloft)
Sildenafil (Viagra)	Sulfamethazine	Sulindac	Talbutal	Temazepam-BZO	Temazepam glucuronide-BZO
Tetracycline	$\Delta^9$ -Tetrahydrocannabinol-THC	$\Delta^8$ -Tetrahydrocannabinol-THC	$\Delta^6$ -Tetrahydrocannabinol	Tetrahydrozoline	Thebaine-OPI, OXY
Theophylline	Thiamine	Thiopental	Thioridazine	Thiothixene	Tolbutamide
Tolmetin (Tolectin)	Trazodone	Triamterene	Triazolam-BZO	Triazolam, 1-hydroxy-BZO	Trifluoperazine
Trimethoprim	Trimipramine	Tripelennamine	Tryptamine	Tryptophan	Tyramine-AMP, MAMP
Tyrosine	Valproic Acid	Venlafaxine	Verapamil	Zomepirac	

### 13D. Related and Reactive Compounds

The following metabolites and compounds were initially dissolved in appropriate solvents and then added at varying concentrations to drug-free urine for evaluation with all nine SURE-SCREEN tests. Samples were evaluated in triplicate by in-house operators. Unless noted in the following tables, the listed compounds gave negative results with all nine of the SURE-SCREEN tests. Results are expressed as the minimum concentration of metabolite or compound required to produce a positive test result with the indicated SURE-SCREEN test. Percent cross reactivity of a compound is calculated by dividing the cutoff concentration by the minimum concentration required to obtain a positive result and then multiplying by 100%.

<b>Amphetamine (d-amphetamine, cutoff = 300 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
I-Amphetamine	Positive at 300 ng/mL	100%
Ephedrine	Positive at 100,000 ng/mL	< 1%
MDA	Negative at 100,000 ng/mL	< 1%
MDE (MDEA)	Positive at 750 ng/mL	40%
MDMA	Negative at 100,000 ng/mL	< 1%
d-Methamphetamine	Negative at 100,000 ng/mL	< 1%
l-Methamphetamine	Negative at 100,000 ng/mL	< 1%
Phenethylamine	Negative at 100,000 ng/mL	< 1%
Phentermine	Positive at 1,000 ng/mL	33%
Tyramine	Negative at 100,000 ng/mL	< 1%

<b>Benzodiazepines (Nordiazepam, cutoff = 200 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
Alprazolam	Positive at 200 ng/mL	100%
Alprazolam, 1-Hydroxy	Positive at 100 ng/mL	200%
7-Amino-clonazepam	Positive at 1,000 ng/mL	20%
7-Amino-flunitrazepam	Negative at 100,000 ng/mL	< 1%
Chlordiazepoxide	Negative at 100,000 ng/mL	< 1%
Clobazam	Positive at 25,000 ng/mL	< 1%
Clonazepam	Positive at 75 ng/mL	267%
Clorazepate	Positive at 500 ng/mL	40%
Desalkylflurazepam	Positive at 250 ng/mL	80%
Desmethyl-chlordiazepoxide	Positive at 250 ng/mL	80%
Desmethylflunitrazepam	Positive at 2,500 ng/mL	8%
Diazepam	Positive at 250 ng/mL	80%
Flunitrazepam	Positive at 250 ng/mL	80%
Flurazepam	Positive at 250 ng/mL	80%
Lorazepam	Negative at 100,000 ng/mL	< 1%
Lorazepam glucuronide	Positive at 2,500 ng/mL	8%
Midazolam	Positive at 500 ng/mL	40%
Nitrazepam	Positive at 1000 ng/mL	20%
Oxazepam	Positive at 100 ng/mL	200%
Oxazepam glucuronide	Positive at 250 ng/mL	80%
Temazepam	Positive at 100 ng/mL	200%
Temazepam glucuronide	Positive at 250 ng/mL	80%
Triazolam	Positive at 250 ng/mL	80%
Triazolam, 1-hydroxy	Positive at 500 ng/mL	40%
	Negative at 100,000 ng/mL	< 1%

<b>Cocaine (Benzoylecgonine, cutoff = 100 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
Cocaine	Positive at 100 ng/mL	100%
Cocaine	Positive at 300 ng/mL	33%
Ecgonine	Positive at 100,000 ng/mL	< 1%
Ecgonine Methyl Ester	Negative at 100,000 ng/mL	< 1%

<b>Methamphetamine (d-Methamphetamine, cutoff = 1000 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
d-Amphetamine	Positive at 1000 ng/mL	100%
l-Amphetamine	Negative at 100,000 ng/mL	< 1%
Ephedrine	Negative at 100,000 ng/mL	< 1%
Fenfluramine	Positive at 2,500 ng/mL	40%
MDA	Positive at 25,000 ng/mL	4%
MDE (MDEA)	Negative at 100,000 ng/mL	< 1%
MDMA	Positive at 5,000 ng/mL	20%
l-Methamphetamine	Positive at 1,500 ng/mL	67%
Phenethylamine	Positive at 7,500 ng/mL	13%
Phentermine	Positive at 5,000 ng/mL	20%
Tyramine	Negative at 100,000 ng/mL	< 1%
<b>Methamphetamine (continued) (d-Methamphetamine, cutoff = 1000 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
Pseudoephedrine	Positive at 1000 ng/mL	100%
Tyramine	Negative at 100,000 ng/mL	< 1%
	Negative at 100,000 ng/mL	< 1%

<b>Methadone (Methadone, cutoff = 200 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
	Positive at 200 ng/mL	100%
EDDP	Negative at 100,000 ng/mL	< 1%
EMDP	Negative at 100,000 ng/mL	< 1%

<b>Opiates (Morphine, cutoff = 100 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
	Positive at 100 ng/mL	100%
Apomorphine	Negative at 100,000 ng/mL	< 1%
Codeine	Positive at 300 ng/mL	33%
Diacetylmorphine	Positive at 300 ng/mL	33%
Dihydrocodeine	Positive at 100 ng/mL	100%
Ethylmorphine	Positive at 50 ng/mL	200%
Hydrocodone	Positive at 300 ng/mL	33%
Hydromorphone	Positive at 100 ng/mL	100%
Levorphanol	Positive at 50,000 ng/mL	< 1%
6-Monoacetylmorphine	Positive at 100,000 ng/mL	< 1%
Morphine 3-β-D-Glucuronide	Positive at 100,000 ng/mL	< 1%
Morphine 6-β-D-Glucuronide	Negative at 100,000 ng/mL	< 1%
Nalorphine	Positive 150 ng/mL	67%
Naloxone	Positive at 25,000 ng/mL	< 1%
Naltrexone	Negative at 100,000 ng/mL	< 1%
Norcodeine	Negative at 100,000 ng/mL	< 1%
Oxycodone	Positive at 50,000 ng/mL	< 1%
Oxymorphone	Positive at 75,000 ng/mL	< 1%
Thebaine	Positive at 1,000 ng/mL	10%

<b>Oxycodone, cutoff= 100 ng/mL</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
	Positive at 100 ng/mL	100%
Apomorphine	Negative at 100,000 ng/mL	< 1%
Codeine	Positive at 2,500 ng/mL	4%
Diacetylmorphine	Negative at 100,000 ng/mL	<1%
Dihydrocodeine	Positive at 2,500 ng/mL	4%
Ethylmorphine	Positive at 2,500 ng/mL	4%
Hydrocodone	Positive at 10,000 ng/mL	1%
Hydromorphone	Positive at 10,000 ng/mL	1%
Levorphanol	Negative at 50,000 ng/mL	<1%
6-Monoacetylmorphine	Negative at 100,000 ng/mL	<1%
Morphine	Positive at 5,000 ng/mL	2%
Morphine 3-β-D-Glucuronide	Negative at 100,000 ng/mL	<1%
Morphine 6-β-D-Glucuronide	Negative at 10,000 ng/mL	1%
Nalorphine	Negative at 100,000 ng/mL	<1%
Naloxone	Positive at 10,000 ng/mL	<1%
Naltrexone	Positive at 25,000 ng/mL	<1%
Norcodeine	Positive at 50,000 ng/mL	<1%
Oxymorphone	Positive at 200 ng/mL	50%
Thebaine	Negative at 100,000 ng/mL	<1%

<b>Phencyclidine (Phencyclidine, cutoff = 25 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
	Positive at 25 ng/mL	100%
4-Hydroxy-Phencyclidine	Positive at 5,000 ng/mL	<1%

<b>THC (Cannabinoids) (11-nor-9-carboxy-Δ<sup>9</sup>-THC, cutoff = 40 ng/mL)</b>	<b>Result</b>	<b>% Cross-Reactivity</b>
	Positive at 40 ng/mL	100%
Cannabidiol	Negative at 100,000 ng/mL	< 1%
Cannabinol	Negative at 100,000 ng/mL	< 1%
l-11-Hydroxy- Δ <sup>9</sup> -THC	Positive at 250 ng/mL	16%
Δ <sup>9</sup> -Tetrahydrocannabinol	Positive at 10,000 ng/mL	< 1%
Δ <sup>8</sup> -Tetrahydrocannabinol (Δ <sup>9</sup> -Tetrahydrocannabinol)	Positive at 25,000 ng/mL	< 1%

### 13E. Interference

#### pH and Specific Gravity:

Every SURE-SCREEN test (Amphetamine, Benzodiazepine, Cocaine, Methamphetamine, Methadone, Opiates, Phencyclidine and Cannabinoids) was assayed with six negative clinical samples with pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. Clearly visible test lines formed with all eight SURE-SCREEN tests within five minutes of the sample contacting the test strip. The affects of these conditions on samples containing drug is not known.

Every SURE-SCREEN test (Amphetamine, Benzodiazepine, Cocaine, Methamphetamine, Methadone, Opiates, Phencyclidine and Cannabinoids) was assayed with seven samples with specific gravity values of 1.003, 1.005, 1.011, 1.016, 1.019, 1.025 and 1.033. Each sample was assayed in triplicate. Clearly visible test lines formed with all eight SURE-SCREEN tests within five minutes of sample contacting the test strip. The affects of these conditions on samples containing drug is not known.

The MEDTOX OXYCODONE test was assayed with six negative clinical samples with pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. The pH samples were fortified with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. All the pH levels gave negative results when fortified to 25 ng/mL, and all pH levels gave positive results when fortified to 150 ng/mL.

The MEDTOX OXYCODONE test was assayed with eight samples with specific gravity values of 1.003, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035 ± 0.001. Each sample was assayed in triplicate. The specific gravity samples were fortified with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. All the specific gravity levels gave negative results when fortified to 25 ng/mL, and all specific gravity levels gave positive results when fortified to 150 ng/mL.

#### Common Drugs:

Following the study of M.L. Smith, et. al.<sup>7</sup> drug free urine samples were spiked with the targeted drugs to the concentrations of 25% and 150% of the cutoff concentrations. 100 µg/mL of the common drugs were then added to the preparation and assayed by SURE-SCREEN. Samples were evaluated in triplicate by in-house operators. None of the common drugs listed in the following table affected the expected results.

**COMMON DRUGS EVALUATED WITH ALL SURE-SCREEN TESTS**

Acetylsalicylic Acid	Chlorpheniramine	Ibuprofen
Acetaminophen	Cocaine-COC	Morphine-OPI
Brompheniramine maleate	Dextromethorphan	Phenobarbital
Caffeine	Diphenylhydantoin	d-Pseudoephedrine
Carbamazepine	Doxylamine	Salicylic Acid

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**15. LIMITED EXPRESS WARRANTIES**

The manufacturer makes no express warranty other than the diagnostic test kit will measure certain drugs and/or drug metabolites when used in accordance with the manufacturer's printed instructions. The use of the kit for any other purpose is outside the intended use of this product. The manufacturer gives no express warranty as to what the legal or clinical significance of the level of drug/drug metabolites detected by the SURE-SCREEN test. The manufacturer disclaims any and all implied warranties of merchantability, fitness for use or implied utility for any other purposes. Any and all damages for failure of the kit to perform to its instructions are limited to the replacement value of the kit.

Covered by one or more patents.

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This product does not contain controlled substances

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