MEDTOX® DIAGNOSTICS, INC.

# SURE-SCREEN®

## PACKAGE INSERT

SURE-SCREEN® is a rapid qualitative screening test for detection of multiple drugs and drug metabolites in human urine. **All SURE-SCREEN® Cup products and SURE-SCREEN®-*d* Dip products are covered by this insert. Refer to product labeling for the drugs assayed by the kit configuration.**

The Lateral Flow (LatFlo®) Adulterant Strip (LFAS) is a rapid qualitative screening assay for the detection of Oxidants and Nitrites and 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, Barbiturates, Benzodiazepines, Cocaine, Methamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, 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) 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 |
| BAR | Barbiturates (Butalbital) | 200 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 |
| PPX | Propoxyphene (Norpropoxyphene) | 300 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:

The amphetamines are a group of drugs that are central nervous system stimulants. This group of compounds includes ‘amphetamine’, ‘methamphetamine’, and related designer drugs like MDMA (Ecstasy).
‘Amphetamine’ (d-amphetamine) is detected on the device only at the (AMP) position. Methamphetamine (d-methamphetamine) is detected on the device at the (MAMP) position.

Barbiturates (BAR) are a group of structurally related prescription drugs that are used to reduce restlessness and emotional tension, induce sleep and to treat certain convulsive disorders.

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.

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®, 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.

Propoxyphene (PPX) is a narcotic analgesic. Its primary metabolite is norpropoxyphene.

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.[1-5]

| Drug | Detection Period |
|---|---|
| Amphetamine | |
| Acid Conditions | 1-3 days |
| Alkaline Condition | 3-10 days |
| Barbiturates | |
| Short-Acting | Up to 6 days |
| Long-Acting | Up to 16 days |
| Benzodiazepines | 1-12 days |
| Cocaine metabolite | Up to 5 days<br>1 to 3 days typical |
| Methadone | 1-3 days |
| Methamphetamine | |
| Acid Conditions | 1-3 days |
| Alkaline Conditions | 3-10 days |

| Drug | Detection Period |
|---|---|
| Opiates | |
| Heroin | 1 day |
| Morphine | 1-3 days |
| Codeine | 1-3 days |
| Oxycodone | 1-3 days |
| PCP | |
| Single Use | 1-8 days |
| Chronic Use | Up to 4 weeks |
| Propoxyphene | Up to 1 week |
| THC | |
| Single Use | 1-7 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 cup is tipped on its side or the dip device is dipped, urine flows into the sample pads of the device, the dried antibody-colloidal gold on the sample pad(s) dissolves and the urine wicks up the white test strips carrying the reddish-purple antibody-colloidal gold with it.

**Negative Samples**
When no drug(s) is present in the urine sample, the reddish-purple 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 test line and a control line are 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 contains all the reagents necessary to test one urine sample for one or more drugs simultaneously. SURE-SCREEN test devices are available in Cup or Dip format as described below.

**Kit Contents – Cup Test format**
The SURE-SCREEN Drugs of Abuse Cup Test kit contains twenty-five (25) test system bags and one reference guide.
Each Cup Test system bag contains:

1. One (1) test device in a foil package.
    1. Each test device has test strips with drug specific reagents.
    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. (Products with LFAS test strip only; 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 Test format**
The SURE-SCREEN Drugs of Abuse Dip Test Kit contains twenty-five (25) test devices in foil packages and one reference guide.
Each Dip Test device has test strips with drug specific reagents.

**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.

**Materials Required but not provided**
Timer
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.

**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. Avoid contact with broken skin.
2. Avoid cross-contamination of urine samples by using a new urine specimen container for each urine sample.
3. The device should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, do not use the test.
4. Do not store the test kit at temperatures above 25°C (77°F).
5. If devices have been stored refrigerated, bring to ambient temperature (18-25°C/ 64-77°F) prior to opening foil pouch.
6. Do not use tests after the expiration date printed on the package label.
7. 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

For a Cup Test, collect the urine sample in the provided cup. The urine volume should be between the minimum and maximum volume lines.
For a Dip Test, collect the urine sample in a clean specimen 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 at 2 to 8°C (36 to 46°F) for no more than two days. Urine may be frozen at -20°C (-4°F) or colder for 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**

1. Bring pouched device to room temperature before opening it. Fill urine sample cup between the minimum and maximum volume lines.
2. Screw lid clockwise onto the cup until very tight.
3. Open pouch and label the device with the patient or sample identification.
4. Connect device to lid securely as follows: Hold cup with raised sample port toward you. Hold device cassette with MEDTOX labeled end to your left. Place device cassette on top of cup lid with holes aligned. Rotate the device clockwise ¼ turn until it snaps in place.
5. Tip the cup on its side to start flow (if less than 45 ml of urine, tilt the cup forward to begin flow).
6. If LFAS is present, read pH, Specific Gravity, and Nitrites in vertical position as soon as color changes. Read oxidant at 60 seconds.
7. Allow the test cup to sit on its side for 5 minutes.
8. Turn the test cup upright and read the results. Control line must be present to read results. Negative results can be read as soon as a test line is visible, non-negatives at 5 minutes.

**Dip Test**

1. Bring pouched device to room temperature before opening it.
2. Open one pouch for each sample to be tested. Write patient or sample identification information on the device.
3. Pull off the clear cover to expose the fiber pads at ends of test strips.
4. Dip the small end of the cassette into the sample so that only the white ends of the test strips are submerged.
5. Hold the ends of the test strips in the sample until the reddish-purple solution begins to run up all of the strips.
6. Remove the device from sample and replace the cover to protect the wet ends of the test strips.
7. Lay cassette flat, face up for 5 minutes.
8. Read the results. Control line must be present to read results. Negative results can be read as soon as a test line is visible, non-negative at 5 minutes.

**NOTE:** Read results at 5 minutes or within 15 minutes of the sample application. Oxycodone should be read at 5 minutes. Test results interpreted after 15 minutes (for Oxycodone after 5 minutes) may not be consistent with the original results obtained at 5 minutes.

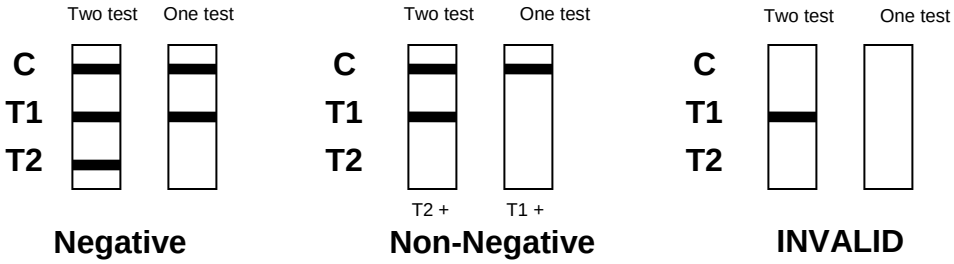
**8. READING THE TEST RESULTS**

**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:




There are other possible results depending on the drug or combination of drugs present in the urine sample.

**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[a]:*

| |
|---|
| *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 not 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.* |

*[a] 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. When in doubt send the urine sample to a reference laboratory for additional testing.

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, barbiturates, benzodiazepines, cocaine, methadone, methamphetamine, opiates, oxycodone, phencyclidine, propoxyphene 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, barbiturates, benzodiazepines, methamphetamine, opiates, oxycodone, propoxyphene or methadone) may appear in the urine for legitimate reasons. Confirmatory test results should be reviewed by a Medical Review Officer for interpretation.

**LFAS Test:**
Urines that produce an abnormal result on the LFAS adulteration strip should be sent to a reference laboratory for more definitive testing to determine if the urine may be dilute, substituted, invalid and/or adulterated.

## 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, Barbiturates, Benzodiazepines, Cocaine, Methamphetamine, Methadone, Opiates, Phencyclidine, Propoxyphene, and Cannabinoids (THC)*)***

| **5 Minute** | 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) |
|---|---|---|---|---|---|
| **AMP** | | | 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. | | | | | |
| **BAR** | | | 109 -194 | 201 - 298 | 326 - 27776 |
| Positive | 0 | Not performed | 3 | 12 | 52 |
| Negative | 58 | Not performed | 5 | 0 | 0 |
| Samples contained one of the following barbiturates: Phenobarbital, Butalbital or Pentobarbital. Ten samples were diluted with negative urine to obtain concentrations around cutoff. | | | | | |
| **BZO** | | | 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 α-hydroxy-alprazolam were added together to determine the total benzodiazepine concentration reported in the table. Six samples were diluted with negative urine to obtain concentrations around the cutoff. | | | | | |
| **COC** | | | 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). | | | | | |
| **MTD** | | | 112 - 114 | 249 - 283 | 307 - 9411 |
| Positive | 0 | Not performed | 2 | 6 | 44 |
| Negative | 98 | Not performed | 2 | 1 | 0 |
| | | | | | |
| **OPI** | | | 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. | | | | | |
| **PCP** | | | 13 - 22 | 27 - 35 | 39 - 5439 |
| Positive | 0 | Not performed | 2 | 5 | 33 |
| Negative | 55 | Not performed | 3 | 0 | 0 |
| | | | | | |
| **PPX** | | | 150-265 | 339-450 | >472 |
| Positive | 0 | Not performed | 4 | 6 | 73 |
| Negative | 60 | Not performed | 4 | 1 | 1 |
| Eight samples were diluted with negative urine to obtain concentrations around the cutoff. | | | | | |
| **THC** | | 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 | |
| **MAMP** | Positive | 56 | 0 | 56 | |
| **(1000 ng/mL** | Negative | 2 | 56 | 58 | |
| **Cut-off)** | 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) |
| **AMP** | | 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. | | | | | |
| **BZO** | | 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 α-hydroxy-alprazolam were added together to determine the total benzodiazepine concentration reported in the table. | | | | | |
| **COC** | | 16-48 | 57-96 | 113-133 | 200-39644 |
| Positive | 1 | 1 | 4 | 5 | 28 |
| Negative | 959 | 2 | 0 | 0 | 0 |
| Samples are categorized by benzoylecgonine concentrations (cocaine metabolite). | | | | | |
| **MTD** | | | | 207 | 335-8377 |
| Positive | 0 | Not performed | Not performed | 1 | 6 |
| Negative | 993 | Not performed | Not performed | 0 | 0 |
| | | | | | |
| **OPI** | | 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. | | | | | |
| **PCP** | | | | | 236-373 |
| Positive | 0 | Not performed | Not performed | Not performed | 4 |
| Negative | 996 | Not performed | Not performed | Not performed | 0 |
| | | | | | |
| **THC** | | 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. | | | | | |

**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**

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.

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

| Barbiturates (Butalbital) Cutoff = 200 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| Negative | 45 | 0 | 45 |
| 50 | 45 | 0 | 45 |
| 100 | 45 | 0 | 45 |
| 150 | 45 | 12 | 33 |
| **200** | 45 | 43 | 2 |
| 250 | 45 | 45 | 0 |
| 300 | 45 | 45 | 0 |

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

| Cocaine (Benzoylecgonine) Cutoff = 100 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| Negative | 540 | 0 | 540 |
| 25 | 45 | 0 | 45 |
| 50 | 45 | 19 | 26 |
| 75 | 45 | 25 | 20 |
| **100** | 45 | 35 | 10 |
| 125 | 45 | 44 | 1 |
| 150 | 45 | 41 | 4 |

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

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

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

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

| Propoxyphene (Norpropoxyphene) Cutoff = 300 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| Negative | 45 | 0 | 45 |
| 30 | 45 | 0 | 45 |
| 75 | 45 | 1 | 44 |
| 150 | 45 | 9 | 36 |
| 225 | 45 | 16 | 29 |
| **300** | 45 | 37 | 8 |
| 375 | 45 | 42 | 3 |
| 450 | 45 | 44 | 1 |
| 600 | 45 | 45 | 0 |

| Cannabinoids (11-nor-9-carboxy-$\Delta^9$-THC) Cutoff = 40 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| Negative | 105 | 0 | 105 |
| 10 | 45 | 0 | 45 |
| 20 | 45 | 0 | 45 |
| 30 | 45 | 1 | 44 |
| **40** | 45 | 45 | 0 |
| 50 | 45 | 40 | 5 |
| 60 | 45 | 45 | 0 |

**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 |

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:

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

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

| Cocaine (Benzoylecgonine) Cutoff = 100 ng/mL | | | |
|---|---|---|---|
| Conc. (ng/mL) | Number Tested | Positive | Negative |
| Negative | 135 | 0 | 135 |
| 25 | 45 | 0 | 45 |
| 50 | 45 | 6 | 39 |
| 100 | 45 | 26 | 19 |
| 125 | 45 | 45 | 0 |

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

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

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

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

**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 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 of the SURE-SCREEN tests.

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

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

The following compounds were tested for reactivity to the SURE-SCREEN Drugs of Abuse Test System. Listed compounds were dissolved in appropriate solvents and then added to drug-free urine for testing. Samples were evaluated in triplicate by in-house operators. Unless otherwise noted by a drug name abbreviation such as "AMP" or "BAR" etc., all of the listed compounds were negative in each of the tests at 100 µg/mL or the highest level tested (Alprazolam, 1-hydroxy; Buprenorphine, Fentanyl, Lorazepam glucuronide, 11-Nor-9-carboxy-$\Delta^9$-THC, Olanzapine, and Oxazepam glucuronide were evaluated at 10µg/mL. 11-Nor-9-carboxy-$\Delta^8$-THC was evaluated at 5 µg/mL). If a drug name is followed by an abbreviation such as "AMP" or "BAR" etc., check the "Related Compounds and Cross Reactants" listing for the drug in question under the appropriate heading (AMP, BAR, etc.) to find its level of cross-reactivity to that test.

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

| | | | | | |
|---|---|---|---|---|---|
| Sildenafil (Viagra) | Sulfamethazine | Sulindac | Talbutal-**BAR** | Temazepam-**BZO** | Temazepam glucuronide-**BZO** |
| Tetracycline | $\Delta^9$-Tetrahydrocannabinol-**THC** | $\Delta^8$-Tetrahydrocannabinol-($\Delta^6$-Tetrahydrocannabinol) **THC** | Tetrahydrozoline | Thebaine-**OPI** | |
| Theophyline | Thiamine | Thiopental | Thioridazine | Thiothixene | Tolbutamide |
| Tolmetin (Tolectin) | Trazodone | Triamterene | Triazolam-**BZO** | Triazolam, 1-hydroxy | Trifluoperazine |
| Trimethoprim | Trimipramine | Tripelennamine | Tryptamine | Tryptophan | Tyramine |
| Tyrosine | Valproic Acid | Venlafaxine | Verapamil | Zomepirac | |

**13D. Related and Reactive Compounds**

The following metabolites and reacting compounds were evaluated for the specified test on the SURE-SCREEN Drugs of Abuse Test System. Reference standards for the various metabolites and compounds were prepared in negative urine samples. Results are expressed as the minimum concentration expected to produce a positive result in the indicated assay. Compounds that reacted with the test are listed first, and related compounds that did not react with the highest concentration tested are listed second as Negative at 100,000 ng/mL (or highest level tested).

| **Amphetamine- (AMP)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (d-Amphetamine) 300 ng/mL | Positive at 300ng/mL | 100% |
| l-Amphetamine | Positive at 100,000 ng/mL | <1% |
| MDA | Positive at 750ng/mL | 40% |
| Phentermine | Positive at 1,000 ng/mL | 30% |
| | | |
| Ephedrine | Negative at 100,000 ng/mL | None Detected |
| MDE (MDEA) | Negative at 100,000 ng/mL | None Detected |
| MDMA | Negative at 100,000 ng/mL | None Detected |
| l-Methamphetamine | Negative at 100,000 ng/mL | None Detected |
| d-Methamphetamine | Negative at 100,000 ng/mL | None Detected |
| Phenethylamine | Negative at 100,000 ng/mL | None Detected |
| Tyramine | Negative at 100,000 ng/mL | None Detected |

| **Barbiturate-(BAR)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Butalbital) 200 ng/mL | Positive at 200 ng/mL | 100% |
| Allobarbital | Positive at 500 ng/mL | 40% |
| Alphenal | Positive at 100 ng/mL | 200% |
| Amobarbital | Positive at 2,500 ng/mL | 8% |
| Barbital | Positive at 2,500 ng/mL | 8% |
| Butabarbital | Positive at 750 ng/mL | 27% |
| Cyclopentobarbital | Positive at 250 ng/mL | 80% |
| p-Hydroxyphenobarbital | Positive at 500 ng/mL | 40% |
| Pentobarbital | Positive at 500 ng/mL | 40% |
| Phenobarbital | Positive at 800 ng/mL | 25% |
| Phenytoin (Diphenylhydantoin) | Positive at 2,500 ng/mL | 8% |
| Secobarbital | Positive at 75 ng/mL | 267% |
| Talbutal | Positive at 50 ng/mL | 400% |
| | | |
| Amino glutethimide | Negative at 100,000 ng/mL | None Detected |
| Barbituric Acid | Negative at 100,000 ng/mL | None Detected |
| 1,3 Dimethylbarbituric Acid | Negative at 100,000 ng/mL | None Detected |
| Glutethimide | Negative at 100,000 ng/mL | None Detected |
| Hexobarbital | Negative at 100,000 ng/mL | None Detected |
| Mephobarbital | Negative at 100,000 ng/mL | None Detected |

| **Benzodiazepine-(BZO)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Nordiazepam) 200 ng/mL | Positive at 200 ng/mL | 100% |
| Alprazolam | Positive at 100 ng/mL | 200% |
| Alprazolam, 1-OH | Positive at 1000 ng/mL | 20% |
| Chlordiazepoxide | Positive at 25,000 ng/mL | <1% |
| Clobazam | Positive at 75 ng/mL | 267% |
| Clonazepam | Positive at 500 ng/mL | 40% |
| Clorazepate | Positive at 250 ng/mL | 80% |
| Desalkylflurazepam | Positive at 250 ng/mL | 80% |
| Desmethylchlordiazepoxide | Positive at 2500 ng/mL | 8% |
| Desmethylflunitrazepam | Positive at 250 ng/mL | 80% |
| Diazepam | Positive at 250 ng/mL | 80% |
| Flunitrazepam | Positive at 250 ng/mL | 80% |
| Lorazepam | Positive at 2,500 ng/mL | 8% |
| Lorazepam glucuronide | Positive at 500 ng/mL | 40% |
| Lysergic acid | Positive at 25,000 ng/mL | <1% |
| Midazolam | Positive at 1,000 ng/mL | 20% |
| Nitrazepam | Positive at 100 ng/mL | 200% |
| Oxazepam | Positive at 250 ng/mL | 80% |
| Oxazepam glucuronide | Positive at 100 ng/mL | 200% |
| Temazepam | Positive at 250 ng/mL | 80% |
| Temazepam glucuronide | Positive at 250 ng/mL | 80% |
| Triazolam | Positive at 500 ng/mL | 40% |
| | | |
| 7-Aminoclonazepam | Negative at 100,000 ng/mL | None Detected |
| 7-Aminoflunitrazepam | Negative at 100,000 ng/mL | None Detected |
| Flurazepam | Negative at 100,000 ng/mL | None Detected |
| Pyrilamine | Negative at 100,000 ng/mL | None Detected |
| Sildenafil | Negative at 100,000 ng/mL | None Detected |
| Sulindac | Negative at 100,000 ng/mlL | None Detected |
| Triazolam, 1-OH | Negative at 100,000 ng/mL | None Detected |

| **Cocaine-(COC)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Benzoylecgonine) 100 ng/mL | Positive at 100 ng/mL | 100% |
| Cocaine | Positive at 300 ng/mL | 33% |
| Ecgonine | Negative at 100,000 ng/mL | None Detected |
| Ecgonine Methyl Ester | Negative at 100,000 ng/mL | None Detected |

| **Methamphetamine-(MAMP)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| **(**d-Methamphetamine) 1000 ng/mL | Positive at 1000 ng/mL | 100% |
| Ephedrine | Positive at 2,500 ng/mL | 40% |
| Fenfluramine | Positive at 25,000 ng/mL | 4% |
| MDE (MDEA) | Positive at 5,000 ng/mL | 20% |
| MDMA | Positive at 1,500 ng/mL | 67% |
| l-Methamphetamine | Positive at 7,500 ng/mL | 13% |
| Phenethylamine | Positive at 5,000 ng/mL | 20% |
| Phenylephrine | Positive at 50,000 ng/mL | <1% |
| Procaine | Positive at 10,000 ng/mL | 1% |
| d-Amphetamine | Negative at 100,000 ng/mL | None Detected |
| l-Amphetamine | Negative at 100,000 ng/mL | None Detected |
| MDA | Negative at 100,000 ng/mL | None Detected |
| Phentermine | Negative at 100,000 ng/mL | None Detected |
| Pseudoephedrine | Negative at 100,000 ng/mL | None Detected |
| Tyramine | Negative at 100,000 ng/mL | None Detected |

| **Methadone-(MTD)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Methadone) 200 ng/mL | Positive at 200 ng/mL | 100% |
| EDDP (Primary metabolite) | Negative at 100,000 ng/mL | None Detected |
| EMDP (Secondary metabolite) | Negative at 100,000 ng/mL | None Detected |

| **Opiates-(OPI)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Morphine) 100 ng/mL | Positive at 100 ng/mL | 100% |
| 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% |
| Nalorphine | Positive at 150 ng/mL | 67% |
| Naloxone | Positive at 25,000 ng/mL | <1% |
| Ofloxacin | Positive at 5,000 ng/mL | 2% |
| Oxycodone | Positive at 50,000 ng/mL | <1% |
| Oxymorphone | Positive at 75,000 ng/mL | <1% |
| Thebaine | Positive at 1,000 ng/mL | 10% |
| Apomorphine | Negative at 100,000 ng/mL | None Detected |
| Morphine 6-β-D-Glucuronide | Negative at 100,000 ng/mL | None Detected |
| Naltrexone | Negative at 100,000 ng/mL | None Detected |
| Norcodeine | Negative at 100,000 ng/mL | None Detected |

| **Oxycodone-(OXY)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Oxycodone) 100 ng/mL | Positive at 100 ng/mL | 100% |
| Codeine | Positive at 2,500 ng/mL | 4% |
| 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% |
| Morphine | Positive at 5,000 ng/mL | 2% |
| 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% |
| Apomorphine | Negative at 100,000 ng/mL | None Detected |
| Diacetylmorphine | Negative at 100,000 ng/mL | None Detected |
| Levorphanol | Negative at 50,000 ng/mL | None Detected |
| 6-Monoacetylmorphine | Negative at 100,000 ng/mL | None Detected |
| Morphine 3-β-D-Glucuronide | Negative at 100,000 ng/mL | None Detected |
| Morphine 6-β-D-Glucuronide | Negative at 100,000 ng/mL | None Detected |
| Nalorphine | Negative at 100,000 ng/mL | None Detected |
| Thebaine | Negative at 100,000 ng/mL | None Detected |

| **Phencyclidine-(PCP)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Phencyclidine) 25 ng/mL | Positive at 25 ng/mL | 100% |
| 4-Hydroxyphencyclidine | Positive at 5,000 ng/mL | <1% |

| **Propoxyphene-(PPX)** | **Result** | **% Cross-Reactive** |
|---|---|---|
| (Norpropoxyphene) 300 ng/mL | Positive at 300 ng/mL | 100% |
| Propoxyphene | Positive at 50 ng/mL | 600% |

| Cannabinoids-(THC) | Result | % Cross-Reactive |
|---|---|---|
| (11-Nor-9-carboxy-$\Delta^9$-THC) 40 ng/mL | Positive at 40 ng/mL | 100% |
| L-11-Hydroxy-$\Delta^9$-THC | Positive at 250 ng/mL | 16% |
| 11-Nor-9-carboxy-$\Delta^8$-THC | Positive at 1,000 ng/mL | 4% |
| $\Delta^9$ –Tetrahydrocannabinol | Positive at 10,000 ng/mL | <1% |
| $\Delta^8$ –Tetrahydrocannabinol ($\Delta^6$-Tetrahydrocannabinol) | Positive at 25,000 ng/mL | <1% |
| Cannabidiol | Negative at 100,000 ng/mL | None Detected |
| Cannabinol | Negative at 100,000 ng/mL | None Detected |

**13E. Interference**

pH and Specific Gravity:

Each listed SURE-SCREEN test (Amphetamine**,** Benzodiazepine, Cocaine, 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 these 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.

Each listed SURE-SCREEN test (Amphetamine**,** Benzodiazepine, Cocaine, 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 these 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.[6] 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, OXY |
| Brompheniramine maleate | Dextromethorphan | Phenobarbital-BAR |
| 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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