



CLIA WAIVED C-Cup Multi-Drug Urine Test Cup

Catalogue No. See Box Label

CLIA CATEGORIZATION: WAIVED
URINE SCREENING TEST RESULTS AT 5 MINUTES

SAFElife™ C-Cup Multi-Drug Urine Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine with below cutoff concentrations and approximate detection time:

| Drug (Identifier) | Calibrator | Cut-off Level | Minimum Detection Time | Maximum Detection Time |
|------------------------------------|---|---------------|------------------------|------------------------|
| Amphetamine (AMP500) | d-Amphetamine | 500 ng/mL | 2-7 hours | 1-2 days |
| Amphetamine (AMP1000) | d-Amphetamine | 1000 ng/mL | 2-7 hours | 1-2 days |
| Secobarbital (BAR) | Secobarbital | 300 ng/mL | 2-4 hours | 1-4 days |
| Buprenorphine (BUP) | Buprenorphine | 10 ng/mL | 4 hours | 1-3 days |
| Oxazepam (BZO) | Oxazepam | 300 ng/mL | 2-7 hours | 1-2 days |
| Cocaine (COC150) | Benzoylcegonine | 150 ng/mL | 1-4 hours | 2-4 days |
| Cocaine (COC300) | Benzoylcegonine | 300 ng/mL | 1-4 hours | 2-4 days |
| EDDP | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 ng/mL | 3-8 hours | 1-3 days |
| Methylenedioxyamphetamine (MDMA) | 3,4-Methylenedioxyamphetamine | 500 ng/mL | 2-7 hours | 2-4 days |
| Methamphetamine (MET500/mAMP500) | D(+)-Methamphetamine | 500 ng/mL | 2-7 hours | 2-4 days |
| Methamphetamine (MET1000/mAMP1000) | D(+)-Methamphetamine | 1000 ng/mL | 2-7 hours | 2-4 days |
| Morphine (MOP/OPI300) | Morphine | 300 ng/mL | 2 hours | 2-3 days |
| Methadone (MTD) | Methadone | 300 ng/mL | 3-8 hours | 1-3 days |
| Morphine (OPI2000) | Morphine | 2000 ng/mL | 2 hours | 2-3 days |
| Oxycodone (OXY) | Oxycodone | 100 ng/mL | 4 hours | 1-3 days |
| Phencyclidine (PCP) | Phencyclidine | 25 ng/mL | 4-6 hours | 7-14 days |
| Propoxyphene (PPX) | d-Propoxyphene | 300 ng/mL | 2 hours | 2-3 days |
| Nortriptyline (TCA) | Nortriptyline | 1000 ng/mL | 8-12 hours | 2-7 days |
| Cannabinoids (THC) | 11-nor-Δ9-THC-9-COOH | 50 ng/mL | 2 hours | Up to 5+ days |

SAFElife™ C-Cup Multi-Drug Urine Test Cup offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is intended for over-the-counter and for prescription use. For *in vitro* diagnostic use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

WARNINGS AND PRECAUTIONS

- The test kit is for external use only.
- Discard after first use. The test kit cannot be used more than once.
- Do not use the test kit beyond expiration date.
- Do not use the test kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.

CONTENT OF THE KIT

- 25 SAFElife™ C-Cup test devices, each in one pouch with desiccant. The desiccants are for storage purposes only and are not used in the test procedure.
- One (1) Package Insert
- 5 Adulteration Color Comparison Charts (If equipped).
- 25 Security Seals
- 25 Pieces of Gloves

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or Clock

STORAGE AND STABILITY

Store at 4°C–30°C (39°F–86°F) in the sealed pouch up to the expiration date. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

Collect urine specimen after minimum detection time following suspected drug use. Urine collection time is very important in detecting any drugs of abuse. Each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the minimum or maximum detection time of each drug in this instruction.

HOW TO COLLECT URINE?

- Remove the test cup from the foil pouch by tearing at the notch. Use it as soon as possible. Instruct the donor to remove the test cup lid and void directly into the test cup until reach the Minimum Urine Level mark (approximately 25 mL). It is acceptable to collect extra volume of urine. If insufficient specimen has been collected, instruct the donor to provide urine specimen again with another new test cup. Wipe off any splashes or spills that may be on the outside of the cup. It is recommended to wear gloves when handling the test cup with urine specimen.
- Observe the temperature strip affixed on the test cup between 2 to 4 minutes after urine is voided into the cup. The temperature between 32°C to 38°C (90°F–100°F) indicates the fresh uncontaminated sample. If the temperature is out of this range, instruct the donor to provide urine specimen again with another new test cup.

HOW TO DO THE TEST?

Test should be performed at room temperature 18°C–30°C (65°F–86°F).

- After the urine has been collected properly, tighten the lid and place the test cup on a flat surface.
- Peel off the label from right to left.
- For the adulteration strip(s) if equipped, read results immediately, or at 30 seconds, or at 45

seconds and compare each adulterant pad to verify pad color is within acceptable range according to the Adulteration Color Comparison Chart. If the results indicate adulteration, do not read the drug test results. Instruct the donor to provide urine specimen again with another new test cup.

- For the drug tests, read the drug test results at 5 minutes. The results can be stable for 30 minutes.



Note: Results after more than 30 minutes may be not accurate and should not be read.

READING THE RESULTS

Negative (-)

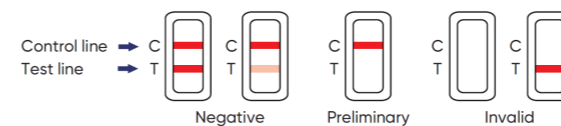
A colored band is visible in each Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)

A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid

If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If the new test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.



Note: There is no meaning attributed to line color intensity or width.

The preliminary positive test result does not always mean that a person took illegal drugs. The negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

What Is the False Positive Test?

The definition of the false positive test would be the instance where a substance is identified incorrectly by SAFElife™ C-Cup Multi-Drug Urine Test Cup. The most common causes of the false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause the false positive test result.

What Is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by SAFElife™ C-Cup Multi-Drug Urine Test Cup. If the specimen is diluted or adulterated, it may cause the false negative result.

If suspect someone is taking drugs but get the negative test results, please test again at another time, or test for different drugs.

ADULTERATION CONTROL

Expected Results

Creatinine (CR): Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex if creatinine in the urine is present at the normal level. The color intensity is directly proportional to the concentration of creatinine. A urine sample with creatinine concentration of less than 20 mg/dl produces a very light, or no pad color change, which indicates adulteration in the form of specimen dilution.

Glutaraldehyde (GL): Glutaraldehyde is not a natural component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, false positive may result when ketone bodies are present in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.

Nitrite (NI): Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dL may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In this adulteration control, nitrite level above 15 mg/dL is considered abnormal.

Oxidants/Bleach (OX): The presence of Bleach and other oxidizing reagents in the urine is indicative of adulteration since oxidizing reagents are not normal constituents of urine. Other oxidizing reagents include Hydrogen Peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate etc.

pH (PH): Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

Specific Gravity (S.G.): The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. The pad colors will change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. A urine specific gravity below 1.003 or above 1.025 is considered abnormal.

TEST LIMITATIONS

- This test kit has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use it to test anything other than urine.
- Adulterated urine samples may produce false results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause false results.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

QUESTIONS AND ANSWERS

- What does the SAFElife™ C-Cup Multi-Drug Urine Test Cup do?*
These tests detect if one or more prescription or illegal drugs such as Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methylenedioxyamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids are present in urine.

The testing is done in two steps. First, test urine with SAFElife™ C-Cup Multi-Drug Urine Test Cup. Second, if any drug test result is preliminary positive, please send the cup with urine to the drug testing laboratory for confirmatory result.

- What is "cut-off level"?*
The cut-off level is the specified concentration of a drug in a urine sample. If the concentration of a drug in urine is above the cutoff concentration, this drug test result will be preliminary positive. If

the concentration of a drug in urine is below the cutoff concentration, this drug test result will be negative.

3. **What are drugs of abuse?**

Drugs of abuse are illegal or prescription drugs (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication longer than doctor prescribed or for a purpose other than what the doctor prescribed.

4. **What are the Common Street Names for the Drugs to be detected?**

| Drug | Common Street Names |
|---------------------------------------|--|
| Amphetamine (AMP) | Speed, Jelly Beans or Super Jellies, Hearts, Uppers, Pick me ups or Wake me ups, Wake ups, Get ups, Boot ups, Sparkles |
| Secobarbital (BAR) | Amytal, Downers, Nembutal, Phenobarbital, Reds, Red Birds, Red devils, Seconal, Tuninal, Yellowjackets |
| Buprenorphine (BUP) | Bupe, Subbies, Temmies |
| Oxazepam (BZO) | Benzos, Downers, Nerve Pills, Tranks |
| Cocaine (COC) | Blow, C, Candy, Coke, Do a line, Freeze, Girl, Happy dust, Mama coca, Mojo, Monster, Nose, Pimp, Shot, Smoking gun, Snow, Sugar, Sweet stuff, and White powder. |
| Methylenedioxymethamp hetamine (MDMA) | Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed |
| Methamphetamine (MET/mAMP) | Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass |
| Methadone (MTD) | mixture, meth, linctus, green |
| Morphine (MOP/OPI300) | Aunt Hazel, big H, black pearl, brown sugar, capital H, charley, china white, dope, good horse, H, hard stuff, hero, heroina, little boy, mud, perfect high, smack, stuff and tar. |
| Oxycodone (OXY) | OC, Ocycotton, OX, and Kicker |
| Phencyclidine (PCP) | Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trunk, white horizon and zoom. |
| Propoxyphene (PPX) | Darvon, Darvocet, Dolene, Propacet 100, Wygesic, SK-65, SK-65 APAP, Trycet, Genagesic, E-Lor, Balacet, Pain Killer, Pinks, Footballs, PP-Cap |
| Nortriptyline (TCA) | Blue angels, Blue birds, Vivactil, Anafranil, Janimine, Tofranil |
| Cannabinoids (THC) | 420, Aunt Mary, baby, bobby, boom, chira, chronic, ditch, ganja, grass, greens, hash, herb, Mary Jane, nigra, Pot, reefer, rip, root, skunk, stack, torch, weed and zambi. |

5. **How accurate is the test?**

The tests are sensitive to drugs and accurate. These tests, however, are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug testing kits.

6. **If the test results are negative, can the conclusion be that the person is free of drugs?**

This means that if the sample was collected properly and if the test was performed according to direction, then none of the drug screened were present in the urine.

7. **Does a preliminary positive screen test mean that drugs of abuse have been found?**

This means that the test has reacted with something in the urine and the urine must be sent to the lab for a more accurate test.

8. **What should I do if the lab test confirms a positive result?**

If you have received a confirmed positive result, please consult with counselor for a proper course of action. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

9. **What is the principle of SAFElife™ C-Cup Multi-Drug Urine Test Cup?**

SAFElife™ C-Cup Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. When the test is activated, the urine is absorbed into the device by capillary action. When flowing across the pre-coated membrane, it will be mixed with the respective drug antibody conjugates. If concentrations of drugs are below corresponding detected drugs' cutoff, respective drug antibody conjugates bind to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. This produces the colored band in Test Region (T) that indicates the negative result. On the contrary, if concentrations of drugs are at or above corresponding detected drugs' cutoff, the free drugs in urine bind to the respective drug antibody conjugates. It prevents the respective drug antibody conjugates from binding to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. Therefore, there is no colored band in the Test Region (T) that indicates the preliminary positive result. To serve as the procedure control, if the test has been performed properly, a colored band will appear at the Control Region (C).

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control line in the test device in the Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment and each new operator to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

Accuracy

1520 (eighty for each drug) clinical urine specimens were analyzed by GC-MS or LC/MS-MS and by each corresponding SAFElife™ C-Cup Multi-Drug Urine Test Cup. Each SAFElife™ C-Cup Multi-Drug Urine Test Cup was read by three viewers. Specimens were divided by concentration into five categories: Drug Free, Less than Half the Cutoff, Near Cutoff Negative, Near Cutoff Positive and High Positive. Results were as followed:

| Drug Test | SAFElife™ C-Cup Result | Drug Free | Less than Half the Cutoff | Near Cutoff Negative (Between 50% below the cutoff and the cutoff) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff) | High Positive (Greater than 50% above the cutoff) | % Agreement with GC/MS or LC/MS |
|-----------|------------------------|-----------|---------------------------|--|--|---|---------------------------------|
| AMP 500 | Viewer A | + 0 0 | 0 17 | 2 11 | 30 0 | 10 0 | 100% 95% |
| | Viewer B | + 0 0 | 0 17 | 1 12 | 30 0 | 10 0 | 100% 97.5% |
| | Viewer C | + 0 0 | 0 17 | 2 11 | 30 0 | 10 0 | 100% 95% |
| AMP 1000 | Viewer A | + 0 0 | 0 16 | 2 12 | 28 2 | 10 0 | 95% 95% |
| | Viewer B | + 0 0 | 0 16 | 2 12 | 28 2 | 10 0 | 95% 95% |
| | Viewer C | + 0 0 | 0 16 | 2 12 | 28 2 | 10 0 | 95% 95% |
| BAR 300 | Viewer A | + 0 0 | 0 19 | 1 10 | 28 1 | 11 0 | 97.5% 97.5% |
| | Viewer B | + 0 0 | 0 19 | 1 10 | 28 1 | 11 0 | 97.5% 97.5% |
| | Viewer C | + 0 0 | 0 19 | 1 10 | 28 1 | 11 0 | 97.5% 97.5% |

| | | | | | | | |
|----------|----------|-------|------|------|------|------|-------------|
| BUP 10 | Viewer A | + 0 0 | 0 18 | 3 9 | 29 1 | 10 0 | 97.5% 92.5% |
| | Viewer B | + 0 0 | 0 18 | 3 9 | 29 1 | 10 0 | 97.5% 92.5% |
| | Viewer C | + 0 0 | 0 18 | 3 9 | 29 1 | 10 0 | 97.5% 92.5% |
| BZO 300 | Viewer A | + 0 0 | 0 15 | 2 13 | 29 1 | 10 0 | 97.5% 95% |
| | Viewer B | + 0 0 | 0 15 | 2 13 | 29 1 | 10 0 | 97.5% 95% |
| | Viewer C | + 0 0 | 0 15 | 2 13 | 29 1 | 10 0 | 97.5% 95% |
| COC 150 | Viewer A | + 0 0 | 0 18 | 1 10 | 31 0 | 9 0 | 100% 95% |
| | Viewer B | + 0 0 | 0 18 | 1 11 | 31 0 | 9 0 | 100% 97.5% |
| | Viewer C | + 0 0 | 0 18 | 2 10 | 31 0 | 9 0 | 100% 95% |
| COC 300 | Viewer A | + 0 0 | 0 13 | 3 14 | 27 2 | 11 0 | 95% 92.5% |
| | Viewer B | + 0 0 | 0 13 | 3 14 | 27 2 | 11 0 | 95% 92.5% |
| | Viewer C | + 0 0 | 0 13 | 3 14 | 27 2 | 11 0 | 95% 92.5% |
| EDDP 300 | Viewer A | + 0 0 | 0 18 | 1 11 | 32 0 | 8 0 | 100% 97.5% |
| | Viewer B | + 0 0 | 0 18 | 1 11 | 32 0 | 8 0 | 100% 97.5% |
| | Viewer C | + 0 0 | 0 18 | 1 11 | 32 0 | 8 0 | 100% 97.5% |
| MDMA 500 | Viewer A | + 0 0 | 0 18 | 2 10 | 30 0 | 10 0 | 100% 95% |
| | Viewer B | + 0 0 | 0 18 | 2 10 | 30 0 | 10 0 | 100% 95% |
| | Viewer C | + 0 0 | 0 18 | 2 10 | 30 0 | 10 0 | 100% 95% |
| MET 500 | Viewer A | + 0 0 | 0 15 | 1 13 | 20 0 | 20 0 | 100% 95% |
| | Viewer B | + 0 0 | 0 15 | 1 14 | 20 0 | 20 0 | 100% 97.5% |
| | Viewer C | + 0 0 | 0 15 | 2 13 | 20 0 | 20 0 | 100% 95% |
| MET 1000 | Viewer A | + 0 0 | 0 18 | 3 9 | 23 2 | 15 0 | 95% 92.5% |
| | Viewer B | + 0 0 | 0 18 | 3 9 | 23 2 | 15 0 | 95% 92.5% |
| | Viewer C | + 0 0 | 0 18 | 3 9 | 23 2 | 15 0 | 95% 92.5% |
| MOP 300 | Viewer A | + 0 0 | 0 18 | 0 12 | 28 2 | 10 0 | 95% 100% |
| | Viewer B | + 0 0 | 0 18 | 0 12 | 28 2 | 10 0 | 95% 100% |
| | Viewer C | + 0 0 | 0 18 | 0 12 | 28 2 | 10 0 | 95% 100% |
| MTD 300 | Viewer A | + 0 0 | 0 18 | 2 10 | 27 1 | 12 0 | 97.5% 95% |
| | Viewer B | + 0 0 | 0 18 | 2 10 | 27 1 | 12 0 | 97.5% 95% |
| | Viewer C | + 0 0 | 0 18 | 2 10 | 27 1 | 12 0 | 97.5% 95% |

| | | | | | | | |
|----------|----------|-------|------|------|------|------|-------------|
| OPI 2000 | Viewer A | + 0 0 | 0 18 | 3 9 | 29 1 | 10 0 | 97.5% 92.5% |
| | Viewer B | + 0 0 | 0 18 | 3 9 | 29 1 | 10 0 | 97.5% 92.5% |
| | Viewer C | + 0 0 | 0 18 | 3 9 | 29 1 | 10 0 | 97.5% 92.5% |
| OXY 100 | Viewer A | + 0 0 | 0 18 | 0 12 | 29 1 | 10 0 | 97.5% 100% |
| | Viewer B | + 0 0 | 0 18 | 0 12 | 29 1 | 10 0 | 97.5% 100% |
| | Viewer C | + 0 0 | 0 18 | 0 12 | 29 1 | 10 0 | 97.5% 100% |
| PCP 25 | Viewer A | + 0 0 | 0 20 | 1 9 | 28 2 | 10 0 | 95% 97.5% |
| | Viewer B | + 0 0 | 0 20 | 1 9 | 28 2 | 10 0 | 95% 97.5% |
| | Viewer C | + 0 0 | 0 20 | 1 9 | 28 2 | 10 0 | 95% 97.5% |
| PPX 300 | Viewer A | + 0 0 | 0 17 | 2 11 | 31 1 | 8 0 | 97.5% 95% |
| | Viewer B | + 0 0 | 0 17 | 2 11 | 31 1 | 8 0 | 97.5% 95% |
| | Viewer C | + 0 0 | 0 17 | 2 11 | 31 1 | 8 0 | 97.5% 95% |
| TCA 1000 | Viewer A | + 0 0 | 0 18 | 2 10 | 29 1 | 10 0 | 97.5% 95% |
| | Viewer B | + 0 0 | 0 18 | 2 10 | 29 1 | 10 0 | 97.5% 95% |
| | Viewer C | + 0 0 | 0 18 | 2 10 | 29 1 | 10 0 | 97.5% 95% |
| THC 50 | Viewer A | + 0 0 | 0 19 | 3 8 | 28 2 | 10 0 | 95% 92.5% |
| | Viewer B | + 0 0 | 0 19 | 3 8 | 28 2 | 10 0 | 95% 92.5% |
| | Viewer C | + 0 0 | 0 19 | 3 8 | 28 2 | 10 0 | 95% 92.5% |

Precision and Sensitivity

To investigate the precision and sensitivity, each drug samples were analyzed at the following concentrations: cutoff -100%, cutoff -75%, cutoff -50%, cutoff -25%, cutoff +25%, cutoff +50%, cutoff +75% and the cutoff +100%. All concentrations were confirmed with GC/MS or LC/MS method. The study was performed 2 runs/day and lasted 25 days using three different lots of the corresponding SAFElife™ C-Cup Multi-Drug Urine Test Cup. Totally 3 operators participated in the study of the corresponding SAFElife™ C-Cup Multi-Drug Urine Test Cup. Each operator tests 2 aliquots at each concentration for each lot per day (2 runs/day) for the total of 50 determinations per concentration per lot of the corresponding SAFElife™ C-Cup Multi-Drug Urine Test Cup.

| Drug Test | Approximate Concentration of Sample (ng/mL) | Number of Determinations per Lot | Results (Negative/Positive) | | |
|-----------|---|----------------------------------|-----------------------------|-------|-------|
| | | | Lot 1 | Lot 2 | Lot 3 |
| AMP 500 | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 125 | 50 | 50/0 | 50/0 | 50/0 |
| | 250 | 50 | 50/0 | 50/0 | 50/0 |
| | 375 | 50 | 50/0 | 50/0 | 50/0 |
| | 500 | 50 | 11/39 | 10/40 | 10/40 |
| | 625 | 50 | 0/50 | 0/50 | 0/50 |
| | 750 | 50 | 0/50 | 0/50 | 0/50 |
| | 875 | 50 | 0/50 | 0/50 | 0/50 |

| | | | |
|---|----------|--|----------|
| Cocaethylene | 12,500 | Norcocaine | >100,000 |
| EDDP 300 | | | |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 | Methadone | 300,000 |
| EMDP | 300,000 | Doxylamine | >100,000 |
| LAAM (Levo-alpha-acetylmethadol) HCl | >100,000 | Alpha Methadol | >100,000 |
| MDMA 500 | | | |
| 3,4-Methylenedioxyamphetamin e (MDMA) | 500 | 3,4-Methylenedioxyethylamphetam ine (MDEA) | 300 |
| 3,4-Methylenedioxyamphetamine (MDA) | 3,000 | d-Methamphetamine | >100,000 |
| l-methamphetamine | 50,000 | l-amphetamine | >100,000 |
| d-amphetamine | >100,000 | | |
| MET 500 | | | |
| d-methamphetamine | 500 | (+/-) 3,4-Methylenedioxyampheta mine (MDMA) | 2,000 |
| p-Hydroxymethamphetamine | 15,000 | (-)-Methamphetamine | 12,500 |
| l-methamphetamine | 10,000 | d-Amphetamine | 25,000 |
| l-Amphetamine | 37,500 | Chloroquine | 10,000 |
| (+/-)-Ephedrine | 25,000 | d/l-Methamphetamine | 500 |
| L-Methamphetamine | 10,000 | (+/-) 3,4Methylenedioxyethylamphet amine (MDEA) | 500 |
| (+/-) 3,4-Methylenedioxyamphetamine (MDA) | 500 | β-Phenylethylamine | 25,000 |
| Trimethobenzamide | 5,000 | d/l-Amphetamine | 75,000 |
| p-Hydroxymethamphetamine | 15,000 | Mephentermine | 25,000 |
| (1R,2S)-(-)-Ephedrine | 50,000 | l-Phenylephrine | 100,000 |
| MET 1000 | | | |
| d-methamphetamine | 1,000 | l-phenylephrine | >100,000 |
| p-Hydroxymethamphetamine | 30,000 | Mephentermine | 50,000 |
| l-methamphetamine | 25,000 | (+/-) 3,4-Methylenedioxyethylamphetam ine (MDEA) | 1,000 |
| D/L-Methamphetamine | 1,000 | D-Amphetamine | 100,000 |
| L-Amphetamine | 75,000 | Chloroquine | 50,000 |
| (+/-)-Ephedrine | 50,000 | (-)-Methamphetamine | 25,000 |
| (+/-) 3,4-Methylenedioxyamphetamine (MDA) | 1,000 | (+/-) 3,4-Methylenedioxyampheta mine (MDMA) | 4,000 |
| β-Phenylethylamine | 50,000 | Trimethobenzamide | 10,000 |
| d,l-Amphetamine | 100,000 | (1R,2S)-(-)-Ephedrine | 100,000 |
| MOP 300 | | | |
| Morphine | 300 | Morphinie-3-β-d-glucuronide | 1,000 |
| Codeine | 300 | Norcodeine | 6,250 |
| Ethyl Morphine | 100 | Normorphine | 300 |
| Heroin | 300 | Oxycodone | 10,000 |
| Hydrocodone | 5,000 | Oxymorphone | 10,000 |
| Hydromorphone | 1,000 | Procaine | 150,000 |
| 6-Monoacetylmorphine (6-MAM) | 150 | Thebaine | 3,000 |
| Levorphanol | 10,000 | | |
| MTD 300 | | | |
| Methadone | 300 | Doxylamine | 50,000 |
| EMDP | >100,000 | EDDP | >100,000 |
| LAAM | >100,000 | Alpha Methadol | >100,000 |
| OPI 2000 | | | |

| | | | |
|------------------------------------|----------|-----------------------------------|----------|
| Morphine | 2,000 | Morphinie-3-β-D-glucuronide | 2,000 |
| Codeine | 2,000 | Norcodeine | 12,500 |
| Ethyl Morphine | 1,500 | Normorphine | 50,000 |
| Heroin | 2,000 | Oxycodone | 25,000 |
| Hydrocodone | 12,500 | Oxymorphone | 25,000 |
| Hydromorphone | 3,500 | Procaine | 150,000 |
| 6-Monoacetylmorphine (6-MAM) | 1,500 | Thebaine | 5,000 |
| Levorphanol | 75,000 | | |
| OXY 100 | | | |
| Oxycodone | 100 | Codeine | 100,000 |
| Dihydrocodeine | 20,000 | Ethyl Morphine | >100,000 |
| Hydrocodone | 10,000 | Hydromorphone | 32,000 |
| Oxymorphone | 1,000 | Thebaine | >100,000 |
| Acetylmorphine | >100,000 | Morphine | >100,000 |
| Buprenorphine | >100,000 | | |
| PCP 25 | | | |
| Phencyclidine | 25 | 4-Hydroxyphencyclidine | 12,500 |
| PPX 300 | | | |
| d-Propoxyphene | 300 | d-Norpropoxyphene | 300 |
| TCA 1000 | | | |
| Nortriptyline | 1,000 | Promazine | 1,500 |
| Amitriptyline | 1,500 | Maprotiline | 2,000 |
| Clomipramine | 12,500 | Nordoxepin | 1,000 |
| Desipramine | 200 | Promethazine | 25,000 |
| Doxepin | 2,000 | Trimipramine | 3,000 |
| Imipramine | 400 | Cyclobenzaprine | 800 |
| Norclomipramine | 12,500 | | |
| THC 50 | | | |
| 11-nor-Δ9-THC-9-COOH | 50 | Δ9-Tetrahydrocannabinol | 5,000 |
| 11-nor-Δ8-THC-9-COOH | 30 | Cannabinol | 20,000 |
| 11-hydroxy-Δ9-Tetrahydrocannabinol | 5,000 | Cannabidiol | 100,000 |
| Δ8-Tetrahydrocannabinol | 1,300 | 11-nor-Δ9-THC-carboxy-glucuronide | 100 |

Effect of Urinary Specific Gravity

The results demonstrate that the urinary specific gravity range of 1.000-1.035 does not affect the test results.

Effect of Urinary pH

The results demonstrate that the range of urinary pH from 4 to 9 does not interfere with the performance of test.

Interfering Substances

The following compounds were added to drug-free urine, urine with drug concentration 25% below the cutoff, and urine with drug concentration 25% above the cutoff for the corresponding SAFElife™ C-Cup Multi-Drug Urine Test Cup. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

| | | |
|----------------------|---------------------------|------------------------|
| (-) Cotinine | Ecgonine Methyl Ester | Nimodipine |
| 3-Hydroxytyramine | Effexor | Norethindrone |
| Acetaminophen | Enalapril Maleate | O-Hydroxyhippuric Acid |
| Acetophenetidin | Epinephrine Hydrochloride | Olanzapine |
| Acetylsalicylic Acid | Erythromycin | Omeprazole |
| Acyclovir | Esomeprazole Magnesium | Ondansetran |
| Afrin | Ethanol | Oxalic Acid |
| Albumin | Fenofibrate | Oxolinic Acid |

| | |
|-------------------------------|----------------------------|
| Aminophylline | Fenoprofen |
| Aminopyrine | Fentanyl Citrate |
| Amiodarone Hydrochloride | Fluoxetine Hydrochloride |
| Amlodipine Mesylate | Fluvoxamine |
| Amoxicillin | Furosemide |
| Ampicillin | Gabapentin |
| Apomorphine | Gentisic Acid |
| Aripiprazole | Glibenclamide |
| Aspartame | Gliclazide |
| Atomoxetine | Glipizide |
| Atorvastatin Calcium | Glucose |
| Atropine | Haloperidol |
| Benzilic Acid | Hemoglobin |
| Benzoic Acid | Ibuprofen |
| Bilirubin | Isosorbide Dinitrate |
| Bupropion | Isoxsuprine |
| Captopril | Ketamine |
| Carbamazepine | Ketoconazole |
| Cefradine | Ketoprofen |
| Cephalexin | Kratom |
| Chloral Hydrate | Labetalol |
| Chloramphenicol | Lamotrigine |
| Chloroquine | Levofloxacin Hydrochloride |
| Chlorothiazide | Levonorgestrel |
| Chlorpheniramine | Levothyroxine Sodium |
| Cholesterol | Lidocaine Hydrochloride |
| Ciprofloxacin Hydrochloride | Lisinopril |
| Citalopram | Lithium Carbonate |
| Clarithromycin | Liverite |
| Clonidine | Loperamide |
| Clopidogrel Hydrogen Sulphate | Loratadine |
| Clozapine | Magnesium |

| | |
|---------------------|----------------------|
| d,l-Propranolol | Maprotiline |
| d,l-Octopamine | Meperidine |
| d,l-Tyrosine | Meprobamate |
| Deoxycorticosterone | Metoprolol Tartrate |
| Dextromethorphan | Mifepristone |
| Diclofenac | Minocycline |
| Dicyclomine | Mirtazapine |
| Diflunisal | Montelukast Sodium |
| Digoxin | Mosapride Citrate |
| Diphenhydramine | N-acetylprocainamide |
| Dirithromycin | Nalidixic Acid |
| d-Norpropoxyphene | Naproxen |
| Domperidone | Niacinamide |
| D-Pseudoephedrine | Nifedipine |
| Duloxetine | Nikethamide |

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

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ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
National Clearinghouse for Alcohol and Drug Information www.health.org 1-800-729-6686
Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS

| | |
|---|--|
|  | Keep away from sunlight |
|  | Store between 4°C - 30°C (39°F - 86°F) |
|  | Keep dry |
|  | Do not re-use |

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