

## CLARITY Multi-Drug Urine Test Cup Package Insert (CLIA WAIVED)

For *in vitro* diagnostic use only.

| INTENDED USE |
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The CLARITY Multi-Drug Urine Test Cup is a rapid visual immunoassay for the qualitative, presumptive detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

| Test                              | Calibrator                         | Cut-off (ng/mL) |
|-----------------------------------|------------------------------------|-----------------|
| Amphetamine (AMP)                 | D-Amphetamine                      | 1,000           |
| Barbiturates (BAR)                | Secobarbital                       | 300             |
| Buprenorphine (BUP)               | Buprenorphine                      | 10              |
| Benzodiazepines (BZO)             | Oxazepam                           | 300             |
| Cocaine (COC)                     | Benzoylcegonine                    | 300             |
| Methylenedioxyamphetamaine (MDMA) | 3,4-Methylenedioxy-methamphetamine | 500             |
| Methamphetamine (MET)             | D-Methamphetamine                  | 1,000           |
| Methadone (MTD)                   | Methadone                          | 300             |
| Morphine (MOP/OPI)                | Morphine                           | 300             |
| Morphine (OPI)                    | Morphine                           | 2,000           |
| Oxycodone (OXY)                   | Oxycodone                          | 100             |
| Phencyclidine (PCP)               | Phencyclidine                      | 25              |
| Propoxyphene (PPX)                | Propoxyphene                       | 300             |
| Nortriptyline (TCA)               | Nortriptyline                      | 1,000           |
| Marijuana (THC)                   | 11-nor-Δ 9 -THC-9-carboxylic acid  | 50              |

The CLARITY 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 for *in vitro* diagnostic use only. It is intended for over-the-counter and for prescription 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. GC/MS or LC/MS is the recommended confirmatory method.

| SUMMARY |
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**AMP (Amphetamine)**

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body’s natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

**BAR (Secobarbital – “Barbiturates”)**

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of Barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine. The detection period for the Barbiturates in the urine is 4-7 days.

**BUP (Buprenorphine)**

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts.

Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/mL after therapeutic administration, but can range up to 20 ng/mL in abuse situations. The plasma half-life of Buprenorphine is 2-4 hours. 1 While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

**BZO (Oxazepam– “Benzodiazepines”)**

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

**COC (Benzoylcegonine – “Metabolite of Cocaine”)**

Cocaine, is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, Cocaine causes fever, unresponsiveness, and difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylcegonine.1,2 Benzoylcegonine, a major metabolite of Cocaine, has a longer biological half-life (5 - 8 hours) than Cocaine (0.5 - 1.5 hours), and can generally be detected for 24-48 hours after Cocaine exposure.

**MDMA (3,4-Methylenedioxy-Metamphetamine - “Ecstasy”)**

Methylenedioxyamphetamaine (Ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlander, 1990). The most pervasive effect of MDMA, occurring in virtually all people who have taken a reasonable dose of the drug, is to produce a clenching of the jaws.

**MET (Methamphetamine)**

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours, and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

**MTD (Methadone)**

Methadone is a narcotic pain reliever for medium to severe pain. It is also used in the treatment of Heroin (Opiate dependence: Vicodin, Percolate, Morphine, etc) addiction. Oral Methadone is very different than the IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like Heroin.

Methadone is a long acting pain reliever producing effects that last between twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal Heroin, from the dangers of injection, and from the emotional roller coaster that most Opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very

long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

**MOP/OPI (Morphine - “Opiate”)**

Opiate refers to any drug that is derived from the opium poppy, including the natural products, Morphine and Codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of Morphine can produce higher tolerance levels and physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

**OXY (Oxycodone)**

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).1 The window of detection for Oxycodone in urine is expected to be similar to that of other opioids such as morphine.

**PCP (Phencyclidine)**

Phencyclidine, also known as PCP, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950’s. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, or tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user’s age, weight, activity, and diet. PCP is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

**PPX (D-Propoxyphene)**

Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. It is prescribed in the United States for the relief of moderate pain. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours). Norpropoxyphene demonstrates substantially less central-nervous system depression than propoxyphene, but shows a greater local anesthetic effect.

**TCA (Nortriptyline – “Tricyclic Antidepressants”)**

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally and sometimes by injection. TCAs are metabolized in the liver, both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

**THC (11-nor-Δ<sup>9</sup>-THC-9-COOH- “Marijuana”)**

THC (Δ<sup>9</sup>-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (Marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking Marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ<sup>9</sup>- tetrahydrocannabinol-9-carboxylic acid (Δ<sup>9</sup>-THC-COOH).

| PRINCIPLE |
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The CLARITY Multi-Drug Urine Test Cup is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against

their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

| COMPOSITION |
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- Each test kit contains Multi-drug urine test cup, disposable glove and package insert.
- Materials required but not provided: timer.

| STORAGE AND STABILITY |
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- Store the test kit in a cool, dry place between 35.6-86°F(2-30°C). Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 59-86°F(15-30°C).
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

*Note: All expiration dates are printed in Year-Month-Day format. 2020-06-18 indicates June 18, 2020.*

| WARNINGS, PRECAUTIONS AND LIMITATIONS |
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- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to local regulations.
- The CLARITY Multi-Drug Urine Test Cup provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

| SPECIMEN COLLECTION AND PREPARATION |
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**1) Urine Assay**

The urine specimen must be collected in a clean and dry container or the test cup provided. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

**2) Specimen Storage**

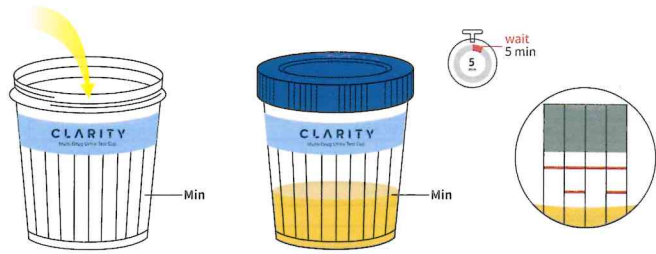
Urine specimens may be stored at 35.6-46.4°F(2-8°C) for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -4°F(-20°C). Frozen specimens should be thawed and mixed before testing.

| TEST PROCEDURE |
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**Allow the test, urine specimen, and/or controls to equilibrate to room temperature 59-86°F(15-30°C) prior to testing.**

- Remove the test cup from the sealed pouch and use it within one hour.
- Open the lid and collect the urine as indicated above, ensuring that the sample is above the minimum fill line.
- After urine has been collected, close the lid securely and place the urine test cup on a flat surface.
- Remove the test window cover along the perforated line.

5. Read the drug test results at 5 minutes. **DO NOT INTERPRET THE RESULTS AFTER 10 MINUTES.**



### INTERPRETATION OF TEST RESULTS

#### NEGATIVE RESULT



A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

NOTE: The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

#### PRELIMINARY POSITIVE RESULT



A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

#### INVALID RESULTS



Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

### QUALITY CONTROL

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.

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Quality Control testing should follow all applicable state, local and federal regulations.

### PERFORMANCE

#### 1. Accuracy

80 clinical urine specimens were analyzed by LC-MS/MS and by the CLARITY Multi-Drug Urine Test Cup. Each test was performed by three operators. Samples 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 follows:

| AMP 1000                             |           |                               |  |  |                                   |  |
|--------------------------------------|-----------|-------------------------------|--|--|-----------------------------------|--|
| CLARITY                              | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |  |
| Operator A                           | Positive  | 0                             | 0  | 17   | 21                                |  |
|                                      | Negative  | 10                            | 15   | 2  | 0                                 |  |
| Operator B                           | Positive  | 0                             | 1  | 19   | 21                                |  |
|                                      | Negative  | 10                            | 14   | 0  | 0                                 |  |
| Operator C                           | Positive  | 0                             | 0  | 18   | 21                                |  |
|                                      | Negative  | 10                            | 15   | 1  | 0                                 |  |
| %Agreement among Positives is 97.5%  |           |                               |  |  |                                   |  |
| %Agreement among Negatives is 99.2%  |           |                               |  |  |                                   |  |
| BAR 300                              |           |                               |  |  |                                   |  |
| CLARITY                              | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |  |
| Operator A                           | Positive  | 0                             | 0  | 17   | 20                                |  |
|                                      | Negative  | 10                            | 16   | 3  | 0                                 |  |
| Operator B                           | Positive  | 0                             | 0  | 18   | 20                                |  |
|                                      | Negative  | 10                            | 16   | 2  | 0                                 |  |
| Operator C                           | Positive  | 0                             | 0  | 19   | 20                                |  |
|                                      | Negative  | 10                            | 16   | 1  | 0                                 |  |
| %Agreement among Positives is 95%    |           |                               |  |  |                                   |  |
| %Agreement among Negatives is 100%   |           |                               |  |  |                                   |  |
| BUP 10                               |           |                               |  |  |                                   |  |
| CLARITY                              | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |  |
| Operator A                           | Positive  | 0                             | 1  | 18   | 20                                |  |
|                                      | Negative  | 10                            | 14   | 2  | 0                                 |  |
| Operator B                           | Positive  | 0                             | 2  | 20   | 20                                |  |
|                                      | Negative  | 10                            | 13   | 0  | 0                                 |  |
| Operator C                           | Positive  | 0                             | 0  | 18   | 20                                |  |
|                                      | Negative  | 10                            | 15   | 2  | 0                                 |  |
| % Agreement among Positives is 96.7% |           |                               |  |  |                                   |  |
| % Agreement among Negatives is 97.5% |           |                               |  |  |                                   |  |
| BZO 300                              |           |                               |  |  |                                   |  |
| CLARITY                              | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |  |
| Operator A                           | Positive  | 0                             | 0  | 15   | 23                                |  |
|                                      | Negative  | 10                            | 15   | 2  | 0                                 |  |
| Operator B                           | Positive  | 0                             | 0  | 16   | 23                                |  |
|                                      | Negative  | 10                            | 15   | 1  | 0                                 |  |
| Operator C                           | Positive  | 0                             | 0  | 17   | 23                                |  |
|                                      | Negative  | 10                            | 15   | 0  | 0                                 |  |
| %Agreement among Positives is 97.5%  |           |                               |  |  |                                   |  |
| %Agreement among Negatives is 100%   |           |                               |  |  |                                   |  |
| COC 300                              |           |                               |  |  |                                   |  |
| CLARITY                              | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |  |

|                                     |           |                               | -50%)  | -50% and the Cutoff)                               | (Between the cutoff and +50%)     | than +50%) |
|-------------------------------------|-----------|-------------------------------|--|--|-----------------------------------|------------|
| Operator A                          | Positive  | 0                             | 0  | 2  | 17                                | 23         |
|                                     | Negative  | 10                            | 14   | 14   | 0                                 | 0          |
| Operator B                          | Positive  | 0                             | 0  | 0  | 15                                | 23         |
|                                     | Negative  | 10                            | 14   | 16   | 2                                 | 0          |
| Operator C                          | Positive  | 0                             | 0  | 1  | 17                                | 23         |
|                                     | Negative  | 10                            | 14   | 15   | 0                                 | 0          |
| %Agreement among Positives is 98.3% |           |                               |  |  |                                   |            |
| %Agreement among Negatives is 97.5% |           |                               |  |  |                                   |            |
| MDMA 500                            |           |                               |  |  |                                   |            |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |            |
| Operator A                          | Positive  | 0                             | 2  | 20   | 20                                |            |
|                                     | Negative  | 10                            | 17   | 11   | 0                                 | 0          |
| Operator B                          | Positive  | 0                             | 0  | 20   | 20                                |            |
|                                     | Negative  | 10                            | 17   | 13   | 0                                 | 0          |
| Operator C                          | Positive  | 0                             | 1  | 20   | 20                                |            |
|                                     | Negative  | 10                            | 17   | 12   | 0                                 | 0          |
| %Agreement among Positives is 100%  |           |                               |  |  |                                   |            |
| %Agreement among Negatives is 97.5% |           |                               |  |  |                                   |            |
| MET 1000                            |           |                               |  |  |                                   |            |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |            |
| Operator A                          | Positive  | 0                             | 0  | 21   | 19                                |            |
|                                     | Negative  | 10                            | 13   | 17   | 0                                 | 0          |
| Operator B                          | Positive  | 0                             | 0  | 19   | 19                                |            |
|                                     | Negative  | 10                            | 13   | 17   | 2                                 | 0          |
| Operator C                          | Positive  | 0                             | 0  | 20   | 19                                |            |
|                                     | Negative  | 10                            | 13   | 17   | 1                                 | 0          |
| %Agreement among Positives is 97.5% |           |                               |  |  |                                   |            |
| %Agreement among Negatives is 100%  |           |                               |  |  |                                   |            |
| MTD 300                             |           |                               |  |  |                                   |            |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |            |
| Operator A                          | Positive  | 0                             | 0  | 18   | 20                                |            |
|                                     | Negative  | 10                            | 16   | 14   | 2                                 | 0          |
| Operator B                          | Positive  | 0                             | 0  | 20   | 20                                |            |
|                                     | Negative  | 10                            | 16   | 12   | 0                                 | 0          |
| Operator C                          | Positive  | 0                             | 1  | 20   | 20                                |            |
|                                     | Negative  | 10                            | 16   | 13   | 0                                 | 0          |
| %Agreement among Positives is 98.3% |           |                               |  |  |                                   |            |
| %Agreement among Negatives is 97.5% |           |                               |  |  |                                   |            |
| MOP/OPI 300                         |           |                               |  |  |                                   |            |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |            |

|                                     |           |                               |  |  | and +50%)                         |    |
|-------------------------------------|-----------|-------------------------------|--|--|-----------------------------------|----|
| Operator A                          | Positive  | 0                             | 0  | 0  | 18                                | 22 |
|                                     | Negative  | 10                            | 14   | 16   | 0                                 | 0  |
| Operator B                          | Positive  | 0                             | 0  | 2  | 18                                | 22 |
|                                     | Negative  | 10                            | 14   | 14   | 0                                 | 0  |
| Operator C                          | Positive  | 0                             | 0  | 0  | 18                                | 22 |
|                                     | Negative  | 10                            | 14   | 16   | 0                                 | 0  |
| %Agreement among Positives is 100%  |           |                               |  |  |                                   |    |
| %Agreement among Negatives is 98.3% |           |                               |  |  |                                   |    |
| OPI 2000                            |           |                               |  |  |                                   |    |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |    |
| Operator A                          | Positive  | 0                             | 0  | 16   | 22                                |    |
|                                     | Negative  | 10                            | 16   | 14   | 2                                 | 0  |
| Operator B                          | Positive  | 0                             | 1  | 18   | 22                                |    |
|                                     | Negative  | 10                            | 16   | 13   | 0                                 | 0  |
| Operator C                          | Positive  | 0                             | 0  | 18   | 22                                |    |
|                                     | Negative  | 10                            | 16   | 14   | 0                                 | 0  |
| %Agreement among Positives is 98.3% |           |                               |  |  |                                   |    |
| %Agreement among Negatives is 99.2% |           |                               |  |  |                                   |    |
| OXY 100                             |           |                               |  |  |                                   |    |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |    |
| Operator A                          | Positive  | 0                             | 2  | 19   | 21                                |    |
|                                     | Negative  | 10                            | 14   | 14   | 0                                 | 0  |
| Operator B                          | Positive  | 0                             | 0  | 18   | 21                                |    |
|                                     | Negative  | 10                            | 14   | 16   | 1                                 | 0  |
| Operator C                          | Positive  | 0                             | 0  | 17   | 21                                |    |
|                                     | Negative  | 10                            | 14   | 16   | 2                                 | 0  |
| %Agreement among Positives is 97.5% |           |                               |  |  |                                   |    |
| %Agreement among Negatives is 98.3% |           |                               |  |  |                                   |    |
| PCP 25                              |           |                               |  |  |                                   |    |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |    |
| Operator A                          | Positive  | 0                             | 1  | 21   | 18                                |    |
|                                     | Negative  | 10                            | 18   | 11   | 1                                 | 0  |
| Operator B                          | Positive  | 0                             | 1  | 21   | 18                                |    |
|                                     | Negative  | 10                            | 18   | 11   | 1                                 | 0  |
| Operator C                          | Positive  | 0                             | 1  | 22   | 18                                |    |
|                                     | Negative  | 10                            | 18   | 11   | 0                                 | 0  |
| %Agreement among Positives is 98.3% |           |                               |  |  |                                   |    |
| %Agreement among Negatives is 97.5% |           |                               |  |  |                                   |    |
| PPX 300                             |           |                               |  |  |                                   |    |
| CLARITY                             | Drug-Free | Low Negative (less than -50%) | Near Cutoff Negative (Between -50% and the Cutoff) | Near Cutoff Positive (Between the cutoff and +50%) | High Positive (greater than +50%) |    |
| Operator A                          | Positive  | 0                             | 0  | 2  | 19                                | 21 |