



## One Step Drug Test

Package Insert for Multi Drug Screen Test Cup

This Instruction Sheet is for testing of any combination of the following drugs:

AMP/BARB/BZO/BUP/COC/THC/MTD/mAMP/MDMA/MOR/OPI/OXY/PCP/PGB/PPX/TC/A/EDDP/6-ACM/COT/K2/K3/K4/KET/KRA/FEN/TRA/ETG/MDPV/ALCO

Including Adulterant Tests (Specimen Validity Tests) for:

Oxidants (OX), Specific Gravity (S.G), pH, Creatinine (CRE), Nitrite (NIT) and Glutaraldehyde (GLU).

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

### For Forensic Use Only

#### INTENDED USE

The **ECO II CUP® One Step Drug Test** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1000)	D-Amphetamine	1,000 ng/mL
Amphetamine (AMP 500)	D-Amphetamine	500 ng/mL
Amphetamine (AMP 300)	D-Amphetamine	300 ng/mL
Barbiturates (BARB)	Butalbital	300 ng/mL
Benzodiazepines (BZO 300)	Oxazepam	300 ng/mL
Benzodiazepines (BZO 200)	Oxazepam	200 ng/mL
Buprenorphine (BUP 10)	Buprenorphine	10 ng/mL
Buprenorphine (BUP 5)	Buprenorphine	5 ng/mL
Cocaine (COC 300)	Benzoyllecgonine	300 ng/mL
Cocaine (COC 150)	Benzoyllecgonine	150 ng/mL
Marijuana (THC 50)	11-nor- $\Delta^9$ -THC-9-COOH	50 ng/mL
Marijuana (THC 20)	11-nor- $\Delta^9$ -THC-9-COOH	20 ng/mL
Marijuana (THC 15)	11-nor- $\Delta^9$ -THC-9-COOH	15 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1000)	D-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	D-Methamphetamine	500 ng/mL
Methamphetamine (mAMP 300)	D-Methamphetamine	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L-Methylenedioxymethamphetamine	500 ng/mL
Opiate (OPI 300, MOP, MOR)	Morphine	300 ng/mL
Opiate (OPI 2000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Pregabalin (PGB)	Pregabalin	2,000 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL
2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP 300)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine	300 ng/mL
2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP 100)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine	100 ng/mL
6-Acetylmorphine (6-ACM)	6-Acetylmorphine	10 ng/mL
Cotinine (COT)	Cotinine	200 ng/mL
Synthetic Cannabinoid (K2 50)	JWH-018 Pentanoic Acid / JWH-073 Butanoic Acid	50 ng/mL
Synthetic Cannabinoid (K2 20)	JWH-018 Pentanoic Acid / JWH-073 Butanoic Acid	20 ng/mL
AB-Pinaca (K3)	AB-Pinaca 5-Pentanoic Acid	10 ng/mL
UR-144 (K4)	UR-144 5-Pentanoic Acid	25 ng/mL
Ketamine (KET)	Ketamine	1,000 ng/mL
Kratom (KRA)	Mitragynine	100 ng/mL
Fentanyl (FEN 10)	Fentanyl	10 ng/mL
Tramadol (TRA 50)	Tramadol	50 ng/mL
Tramadol (TRA 100)	Tramadol	100 ng/mL
Ethyl Glucuronide (ETG 500)	Ethyl Glucuronide	500 ng/mL
Ethyl Glucuronide (ETG 300)	Ethyl Glucuronide	300 ng/mL
Methylenedioxypropylvalerone (MDPV)	Methylenedioxypropylvalerone	1,000 ng/mL
Alcohol (ALCO)	Alcohol	>0.04%

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>1</sup> Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

#### SUMMARY AND EXPLANATION OF THE TEST

The **ECO II CUP® One Step Drug Test** is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine without the use of an instrument.

##### AMPHETAMINE (AMP 1000)

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.

The AMP 1000 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Amphetamine in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>3</sup>

##### AMPHETAMINE (AMP 500)

See AMPHETAMINE (AMP 1000) for the summary.

The AMP 500 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Amphetamine in urine exceeds 500 ng/mL.

##### AMPHETAMINE (AMP 300)

See AMPHETAMINE (AMP 1000) for the summary.

The AMP 300 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Amphetamine in urine exceeds 300 ng/mL.

##### BARBITURATES (BARB)

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 can 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 approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days<sup>1</sup>

The BARB assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Butalbital in urine exceeds 300 ng/mL.

##### BENZODIAZEPINES (BZO 300)

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.

The BZO 300 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Oxazepam in urine exceeds 300 ng/mL.

##### BENZODIAZEPINES (BZO 200)

See BENZODIAZEPINES (BZO 300) for the summary

The BZO 200 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Oxazepam in urine exceeds 200 ng/mL.

##### BUPRENORPHINE (BUP 10)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, perioperative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, and a Buprenorphine/Naloxone combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

The BUP 10 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/mL.

##### BUPRENORPHINE (BUP 5)

See BUPRENORPHINE (BUP 10) for the summary.

The BUP 5 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Buprenorphine in urine exceeds 5 ng/mL.

##### COCAINE (COC 300)

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, 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 Benzoyllecgonine.<sup>1,2</sup> Benzoyllecgonine, 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.<sup>2</sup>

The COC 300 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Benzoyllecgonine in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>3</sup>

##### COCAINE (COC 150)

See COCAINE (COC 300) for the summary.

The COC 150 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of Benzoyllecgonine in urine exceeds 150 ng/mL.

##### MARIJUANA (THC 50)

THC ( $\Delta^9$ -tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC 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 marijuana administered by smoking 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- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid (11-nor- $\Delta^9$ -THC-9-COOH).

The THC 50 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of 11-nor- $\Delta^9$ -THC-9-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>3</sup>

##### MARIJUANA (THC 20)

See MARIJUANA (THC 50) for the summary.

The THC 20 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of 11-nor- $\Delta^9$ -THC-9-COOH in urine exceeds 20 ng/mL.

##### MARIJUANA (THC 15)

See MARIJUANA (THC 50) for the summary.

The THC 15 assay contained within the **ECO II CUP® One Step Drug Test** yields a positive result when the concentration of 11-nor- $\Delta^9$ -THC-9-COOH in urine exceeds 15 ng/mL.

**METHADONE (MTD)**

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use, IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from 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.<sup>4</sup>

The MTD assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Methadone in urine exceeds 300 ng/mL.

**METHAMPHETAMINE (mAMP 1000)**

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 as amphetamine and oxidized and delaminated 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.

The mAMP 1000 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Methamphetamine in urine exceeds 1,000 ng/mL.

**METHAMPHETAMINE (mAMP 500)**

See METHAMPHETAMINE (mAMP 1000) for the summary.  
The mAMP 500 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Methamphetamine in urine exceeds 500 ng/mL.

**METHAMPHETAMINE (mAMP 300)**

See METHAMPHETAMINE (mAMP 1000) for the summary.  
The mAMP 300 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Methamphetamine in urine exceeds 300 ng/mL.

**METHYLENEDIOXYMETHAMPHETAMINE (MDMA)**

Methylenedioxymethamphetamine (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 took a reasonable dose of the drug, was to produce a clenching of the jaws.

The MDMA assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

**OPIATE (OPI 300, MOR, MOP)**

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semisynthetic 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, 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.<sup>4</sup> The OPI 300 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Morphine in urine exceeds 300 ng/mL.

**OPIATE (OPI 2000)**

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semisynthetic 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, 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.<sup>4</sup> The OPI 2000 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>3</sup>

**OXYCODONE (OXY)**

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semisynthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, pupillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast® (immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours). The OXY assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Oxycodone in urine exceeds 100ng/mL.

**PHENCYCLIDINE (PCP)**

Phencyclidine, also known as PCP or Angel Dust, 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, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly 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 phencyclidine. 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.<sup>5</sup> Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).<sup>6</sup> The PCP assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<sup>3</sup>

**PREGABALIN (PGB)**

Pregabalin, sold under the trade name Lyrica®, an analog of the inhibitory neurotransmitter gamma-aminobutyric acid and also of gabapentin, has been used clinically since 2002 as an analgesic, anticonvulsant and anxiolytic agent. It is supplied as the free drug in 25-300mg capsules for oral administration. Adult dose are normally within a range of 50-200mg thrice daily. A single oral labeled dose of pregabalin in humans was eliminated in urine (92%) and feces (<0.1%) over a 4 days period. Urinary excretion products included unchanged drug (90% of the dose), N-Methylpregabalin (0.9%) and others. Single oral 75 or 150mg doses given to a healthy human yielded peak urinary pregabalin concentrations of 151 or 214 µg/mL, respectively, in the first 8 hours specimen. Pregabalin urine levels in 57,542 specimens from chronic pain patients averaged 184 µg/mL<sup>1,2</sup>. The PGB assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of pregabalin in urine exceeds 2000 ng/mL.

**PROPOXYPHENE (PPX)**

Propoxyphene is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity. The PPX assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL.

**TRICYCLIC ANTIDEPRESSANTS (TCA)**

Tricyclic Antidepressants (TCA) 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 or 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. The TCA assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL.

**2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPIRROLIDINE (EDDP 300)**

EDDP is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. EDDP, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized EDDP conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the EDDP level exceeds 300 ng/mL because it will saturate all the binding sites of anti-EDDP antibodies. A drug-positive urine specimen will not generate a colored line in the test line region, 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. The EDDP 300 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of 2-Ethylidene-1,5-Dimethyl-3,3-Dipheylpyrrolidine in urine exceeds 300ng/mL.

**2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPIRROLIDINE (EDDP 100)**

See 2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPIRROLIDINE (EDDP300) for the summary.  
The EDDP 100 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of 2-Ethylidene-1,5-Dimethyl-3,3-Dipheylpyrrolidine in urine exceeds 100 ng/mL.

**6-ACETYLMORPHINE (6-ACM)**

6-AcetylMorphine (6-ACM) is one of three active metabolites of heroin (diacetylMorphine), the others being morphine and the much less active 3-acetylMorphine (3-ACM). 6-ACM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opiate used. This is significant because in a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-ACM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-ACM guarantees that heroin was in fact used as recently as within the last day. The 6-ACM assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of 6-AcetylMorphine in urine exceeds 10 ng/mL.



COTININE (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.<sup>1</sup> While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.<sup>2</sup> Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use. The COT assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Cotinine in urine exceeds 200 ng/mL.

SYNTHETIC CANNABINOIDS (K2 50)

Since 2004, herbal mixtures such as "Spice" have been sold in Switzerland, Austria, Germany and other European countries mainly via Internet shops. Although declared as incense, they are smoked as "bio-drugs" by the consumers. In corresponding blogs, drug users reported cannabis-like effects after smoking. These products enjoy great popularity particularly among younger people, as up to now the mixtures are sold in head shops and via internet in many countries without age restriction.<sup>10</sup> JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. <sup>11</sup> JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", and "K3". <sup>12</sup> These products may be smoked for their psychoactive effects. The K2 50 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Synthetic Cannabinoid compounds in urine exceeds 50 ng/mL.

SYNTHETIC CANNABINOIDS (K2 20)

See SYNTHETIC CANNABINOIDS (K2 50) for the summary. The K2 20 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Synthetic Cannabinoid compounds in urine exceeds 20 ng/mL.

AB-PINACA(K3)

See SYNTHETIC CANNABINOIDS (K2 50) for the summary. The K3 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of AB-Pinaca in urine exceeds 10 ng/mL.

UR-144 (K4)

See SYNTHETIC CANNABINOIDS (K2 50) for the summary. The K4 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of UR-144 5-Pentanoic Acid in urine exceeds 25 ng/mL.

KETAMINE (KET)

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP (Angel Dust). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately an 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours. The KET assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Ketamine in urine exceeds 1,000 ng/mL.

KRATOM (KRA)

Kratom is from a leaf of the kratom plant, it's a natural narcotic produced mainly in southern Thailand, containing mitragynine and 7-Hydroxymitragynine. It is often used to relieve chronic diseases, alcohol, etc., and relieve the pain caused by withdrawal of opium. A pain-eating cocktail made from the pain bearing leaves is the most common and readily available drug drink in southern Thailand. It can cause drowsiness and paralysis. The KRA assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of mitragynine in urine exceeds 100 ng/mL.

FENTANYL (FEN 10)

Fentanyl is a potent, synthetic opioid analgesic with a rapid onset and short duration of action.<sup>13</sup> It is a strong agonist at the μ-opioid receptors. Historically, it has been used to treat breakthrough pain and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine. Fentanyl is approximately 80 to 100 times more potent than morphine and roughly 15 to 20 times more potent than heroin.<sup>14,15</sup> Fentanyl and its derivatives are used recreationally. Deaths have resulted from both recreational and improper medical use.<sup>16</sup> The FEN 10 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Fentanyl in urine exceeds 10 ng/mL.

TRAMADOL (TRA)

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The TRA assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Tramadol in urine exceeds 50 ng/mL.

METHYLENEDIOXYPYROVALERONE (MDPV)

"Bath salts", a form of designer drugs, also promoted as "plant food" or "research chemicals", is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised as "legal" highs. The technical term for "bath salts" is substituted cathinone. Substituted cathinones are synthetic, concentrated versions of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of "bath salts". In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinones, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada. Established as one of the main ingredients for "bath salts", among other synthetic stimulants like Mephedrone, Methyldone, Butylone and Methadone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulants. While synthetic stimulants appear to affect users in ways similar to amphetamines, ecstasy and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. These negative effects have resulted in an increase of ER visits and hospitalizations, severe psychotic and violent episodes, self-inflicted wounds, suicide and an alarming increase in abuse-related deaths. U.S. Poison Control and National Drug Intelligence have all issued health warnings, noting nationwide emergency room visits related to these drugs. In October 2011, the DEA announced an emergency ban on MDPV, Methyldone and Mephedrone, making testing for these substances more vital than ever. The MDPV assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Methylenedioxypropylvalerone in urine exceeds 1,000 ng/mL.

ETHYL GLUCURONIDE (ETG 500)

Ethyl Glucuronide (ETG) is a direct metabolite of ethanol, which is formed by enzymatic conjugation of ethanol with glucuronic acid.<sup>20,21</sup> Alcohol in urine is normally detected for only a few hours, whereas ETG can be detected up to several days even after complete elimination of alcohol from the body.<sup>22</sup> Therefore, ETG can be a useful diagnostic biomarker for determining recent alcohol use and in monitoring abstinence in alcoholics in alcohol withdrawal treatment programs.<sup>23-26</sup> Ethanol can be produced *in vitro* due to fermentation of urine samples containing sugars, bacteria or yeast when samples are exposed to warm temperatures.<sup>27</sup> In such cases, ETG test can be used, as a confirmatory test to determine if the alcohol in the sample is due to consumption of alcohol or it is formed *in vitro* as a result of fermentation. Currently ETG is monitored by GC/MS and LC/MS/MS.<sup>28,29</sup> Ethyl glucuronide (ETG) is a minor non-oxidative metabolite of ethyl alcohol formed by the *in vivo*

conjugation of ethanol with glucuronic acid with UDP glucuronosyltransferase. ETG is a product of metabolic process of ingested alcohol (ethanol) rapidly metabolized in the body, which is excreted in the blood, hair and urine. By using, the *ECO II CUP® One Step Drug Test* ETG can be detected in urine, confirming the consumption of alcohol. The ETG metabolite remains in the body longer and therefore has a more useful window of detection of 8 to 80 hours. ETG testing is an excellent option for zero-tolerance alcohol consumption or for rehabilitation programs. The ETG 500 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Ethyl Glucuronide in urine exceeds 500 ng/mL.

ETHYL GLUCURONIDE (ETG 300)

See ETHYL GLUCURONIDE (ETG 500) for the summary. The ETG 300 assay contained within the *ECO II CUP® One Step Drug Test* yields a positive result when the concentration of Ethyl Glucuronide in urine exceeds 300 ng/mL.

ALCOHOL (ALCO)

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Urine alcohol test is intended for use as a rapid method to detect the presence of alcohol in urine greater than 0.04%. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The adulterant test strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for oxidants, specific gravity, pH, creatinine, nitrite and glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

ADULTERATION

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants, nitrite, glutaraldehyde and creatinine in urine are considered to be the best ways to test for adulteration or dilution.

- Oxidants (OX): Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- Specific Gravity (S.G.): Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.
- Nitrite (NIT): Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- Glutaraldehyde (GLU): Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- Creatinine (CRE): Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

PRINCIPLE

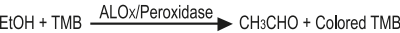
(1) *ECO II CUP® One Step Drug Test* is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not

form in the test line region.

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 will generate a line in the test line region because of the absence of drug competition.

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.

(2) Alcohol test is based on the high specificity of alcohol oxidase (ALOX) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:



The distinct color on reactive pad could be observed in less than 60 seconds after the reaction pad was wetted with urine specimens with the ethyl alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in human urine.

REAGENTS

- (1) The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polydonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to individual drug on the list in the "Intended Use" section.
- (2) The alcohol pad contains tetramethylbenzidine, alcohol oxidase, peroxidase, buffer and stabilizing proteins.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.36%	99.64%
Specific Gravity (S.G.)	0.25%	99.75%
pH	0.06%	99.94%
Nitrite (NIT)	0.07%	99.93%
Glutaraldehyde (GLU)	0.02%	99.98%
Creatinine (CRE)	0.04%	99.96%

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- The test is for single use.
- While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood<sup>9</sup>, the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test cup and urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C (39-86°F). The test is stable through the expiration date printed on the sealed pouch. The test cup must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

**Urine Assay**

The urine specimen should be collected into the test cup. Urine collected at any time of the day may be used. If the urine specimen is collected for later testing, another dry and clean container must be used to collect the specimen. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

SPECIMEN STORAGE

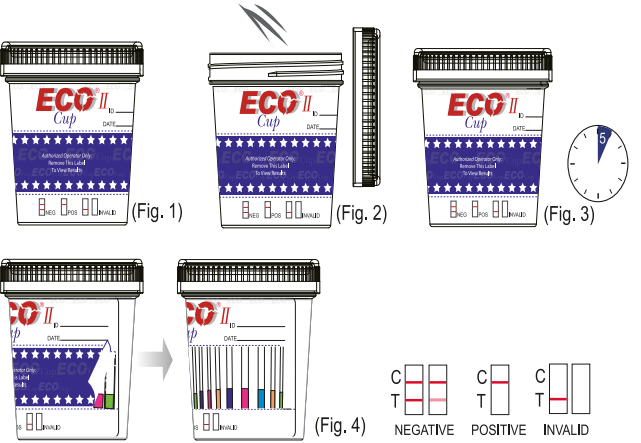
Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

- Materials Provided**
- Test cup
  - Desiccants
  - Package insert
  - Procedure card
  - Color chart card for alcohol and adulterant interpretation (when applicable)
- Materials Required But Not Provided**
- Timer
  - Disposable gloves

DIRECTIONS FOR USE

- Allow the test cup, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.
- 1) Tear the foil pouch open, remove test cup, and donor needs to obtain their own disposable gloves. Label the test cup with donor information. (Fig. 1)
  - 2) Wear disposable gloves to collect urine specimen. Open test cup lid. Urinate directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30mL to maximum 90mL (marked on the cup). (Fig. 2)
  - 3) After urine specimen has been collected, close the lid securely and return cup to collection official. (Fig. 3)
  - 4) The collection official will use newly obtained gloves to peel off the label to reveal test results. Read results of alcohol test at 2 minutes, adulterant test at 3 minutes, and drug tests at 5 minutes. DO NOT INTERPRET ALCOHOL, ADULTERANT AND DRUG TESTS RESULTS AFTER 5 MINUTES. (Fig. 4)



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

**NEGATIVE:** Two lines appear. \* One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

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

**POSITIVE:** One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

**INVALID:** 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 cup. If the problem persists, discontinue using the lot immediately and contact your supplier.

**ALCOHOL TEST RESULTS**

(Please refer to the alcohol color chart)

**NEGATIVE:** Almost no color change by comparing with the background. The negative result indicates that the alcohol concentration is less than 0.04%.

**POSITIVE:** A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.04% or higher.

**INVALID:** The test should be considered invalid if only the edge of the reactive pad turned color that might be attributed to insufficient sampling. The subject should be retested.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color indicator on the color chart. No instrumentation is required.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) LIMITATIONS

1. The adulterant tests included with the product are meant to aid in the determination of abnormal specimens, but may not cover all the possible adulterants.
2. Oxidants: Normal human urine should not contain oxidants. The presence of high level of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Is not normally found in a urine specimen. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine: Tests for the specimen for dilution and flushing. Normal creatinine levels are between 20 and 350mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The **ECO II CUP® One Step Drug Test** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. <sup>3,4,7</sup>
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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 and a new test cup.
4. A positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.
8. Alcohol test is designed for use with human urine only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.
9. There is a possibility that technical or procedure error for alcohol test as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to "Analytical Specificity" section for alcohol test list of substances that will interfere the test results.
10. Alcohol test is a semi-quantitative assay. It identifies alcohol in human urine specimens at a concentration of 0.04% or higher.

PERFORMANCE CHARACTERISTICS

**Accuracy**

In the comparison study, the **ECO II CUP® One Step Drug Test** was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for each of the drug types list on the following table. Clinical specimens were quantified by GC/MS analysis before testing.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine





METHAMPHETAMINE (mAMP 1000)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
250	30	30 negative	>99%
375	15	15 negative	>99%
625	15	12 positive	>80%
750	30	30 positive	>99%
1000	30	30 positive	>99%

METHAMPHETAMINE (mAMP 300)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymeth-amphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
375	40	40 negative	>99%
500	40	40 positive	>99%
750	40	40 positive	>99%

OPIATE (OPI 300, MOP, MOR)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
375	40	40 positive	>99%

OPIATE (OPI 2000)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
1,000	40	40 negative	>99%
1,500	40	40 negative	>99%
2,000	40	40 positive	>99%
3,000	40	40 positive	>99%

OXYCODONE (OXY)

Oxycodone conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
50	40	40 negative	>99%
75	40	40 negative	>99%
100	40	40 positive	>99%
150	40	40 positive	>99%

PHENCYCLIDINE (PCP)

Phencyclidine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
12.5	40	40 negative	>99%
19	40	40 negative	>99%
25	40	40 positive	>99%
37.5	40	40 positive	>99%

PREGABALIN (PGB)

Pregabalin conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
1000	60	60 negative	>99%
3000	60	60 positive	>99%

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPYRROLIDINE (EDDP 300)

EDDP conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
150	60	60 negative	>99%
450	60	60 positive	>99%
600	60	60 positive	>99%

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPYRROLIDINE (EDDP 100)

EDDP conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
50	60	60 negative	>99%
150	60	60 positive	>99%

6-ACETYLMORPHINE (6-ACM)

6-Acetylmorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
5	40	40 negative	>99%
15	40	40 positive	>99%
20	40	40 positive	>99%

BUPRENORPHINE (BUP 10)

Buprenorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%
20	60	60 positive	>99%

BUPRENORPHINE (BUP 5)

Buprenorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
2.5	60	60 negative	>99%
7.5	60	60 positive	>99%

PROPOXYPHENE (PPX)

Propoxyphene conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
150	60	60 negative	>99%
450	60	60 positive	>99%
600	60	60 positive	>99%

KETAMINE (KET)

Ketamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	24	24 negative	>99%
500	24	24 negative	>99%
1,000	24	24 positive	>99%
1,500	24	24 positive	>99%

KRATOM (KRA)

Kratom conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
50	60	60 negative	>99%
150	60	60 positive	>99%

COTININE (COT)

Cotinine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
100	60	60 negative	>99%
400	60	60 positive	>99%

SYNTHETIC CANNABINOID (K2 50)

JWH-018 Pentanoic Acid/ JWH-073 Butanoic Acid conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
25	60	60 negative	>99%
75	60	60 positive	>99%

SYNTHETIC CANNABINOID (K2 20)

JWH-018 Pentanoic Acid/ JWH-073 Butanoic Acid conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
10	60	60 negative	>99%
30	60	60 positive	>99%

AB-PINACA(K3)

AB-Pinaca 5-Pentanoic Acid conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%

UR-144 (K4)

UR-144 5-Pentanoic Acid conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
12.5	60	60 negative	>99%
37.5	60	60 positive	>99%



FENTANYL (FEN 10)			
Fentanyl conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%

TRAMADOL (TRA 50)			
Tramadol conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
25	60	60 negative	>99%
75	60	60 positive	>99%

TRAMADOL (TRA100)			
Tramadol conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
50	60	60 negative	>99%
150	60	60 positive	>99%

METHYLENEDIOXYPYROVALERONE (MDPV)			
Methylenedioxypyrovalerone conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
500	60	60 negative	>99%
1500	60	60 positive	>99%

ETHYL GLUCURONIDE (ETG 300)			
Ethyl Glucuronide conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	70	70 negative	>99%
150	70	70 negative	>99%
450	70	70 positive	>99%
600	70	70 positive	>99%

ETHYL GLUCURONIDE (ETG 500)			
Ethyl Glucuronide conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	70	70 negative	>99%
250	70	70 negative	>99%
750	70	70 positive	>99%

### Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP 1000		BZO 300		BZO 200		COC 300		THC 50		PCP		TCA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	MTD		mAMP1000		mAMP 300		MDMA		MOR		OPI		OXY		K2 50		K2 20	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	AMP 300		COC 150		THC 20		mAMP 500		n	K3		K4		KRA		PGB	
		-	+	-	+	-	+	-	+		-	+	-	+	-	+	-	+
0% Cut-off	25	25	0	25	0	25	0	25	0	30	30	0	30	0	30	0	30	0
-50% Cut-off	25	25	0	25	0	25	0	25	0	30	30	0	30	0	30	0	30	0
-25% Cut-off	25	25	0	25	0	25	0	25	0	30	30	0	30	0	30	0	30	0
Cut-off	25	1	24	3	22	2	23	2	23	30	3	27	3	27	3	27	2	28
+25% Cut-off	25	0	25	0	25	0	25	0	25	30	0	30	0	30	0	30	0	30
+50% Cut-off	25	0	25	0	25	0	25	0	25	30	0	30	0	30	0	30	0	30

Drug concentration Cut-Off Range	n	BUP 10		PPX		EDDP 300		6-ACM		AMP500		COT		n	ETG300		BUP5	
		-	+	-	+	-	+	-	+	-	+	-	+		-	+	-	+
0% Cut-off	90	90	0	90	0	90	0	90	0	90	0	90	0	30	30	0	30	0
-50% Cut-off	90	90	0	90	0	90	0	90	0	90	0	90	0	30	30	0	30	0
-25% Cut-off	90	81	9	81	9	78	12	80	10	81	9	90	0	30	30	0	30	0
Cut-off	90	48	42	44	46	41	49	46	44	45	45	63	27	30	3	27	3	28
+25% Cut-off	90	11	79	12	78	15	75	12	78	10	80	40	50	30	1	29	1	29
+50% Cut-off	90	0	90	0	90	0	90	0	90	0	90	16	74	30	0	30	0	30
2X Cut-off	90	0	90	0	90	0	90	0	90	0	90	0	90	30	0	30	0	30

Drug concentration Cut-off Range	n	FEN 10		TRA 50		TRA100		MDPV		ETG500		THC15		EDDP 100		BARB	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	29	1	30	0	30	0	30	0	30	0	30	0
Cut-off	30	2	28	2	28	0	30	2	28	3	27	3	27	1	29	1	29
+25% Cut-off	30	0	30	0	30	0	30	0	30	1	29	1	29	0	30	0	30
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	KET	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
Cut-off	30	0	30
+50% Cut-off	30	0	30

### Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the ***ECO II CUP® One Step Drug Test*** at a read time of 5 minutes.

Drug	Concentration (ng/mL)
AMPHETAMINE (AMP 1000)	
d-amphetamine	1,000
D,l-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)-Methylenedioxyamphetamine	1,500
AMPHETAMINE (AMP 500)	
d-amphetamine	500
D,l-amphetamine	750
l-amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine	800
AMPHETAMINE (AMP 300)	
d-amphetamine	300
D,l-amphetamine	500

l-amphetamine	10,000
Phentermine	400
(+/-)-Methylenedioxyamphetamine	500
Barbiturates (BARB)	
Butalbital	300
Secobarbital	1500
Amobarbital	10000
Alphenal	120
Aprobarbital	500
Allobarbital	500
Butabarbital	250
Butethal	500
Cyclopentobarbital	62.5
Pentobarbital	5000
Phenobarbital	250

BENZODIAZEPINES (BZO 300)	
a-Hydroxyalprazolam	1,260
Alprazolam	200
Bromazepam	1,560
Chlordiazepoxide	1,585
Chlordiazepoxide HCl	780
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	300
Temazepam	100
Triazolam	2,500

BENZODIAZEPINES (BZO 200)	
a-Hydroxyalprazolam	840
Alprazolam	134
Bromazepam	1,040
Chlordiazepoxide	1,043
Chlordiazepoxide HCl	520
Clobazam	67
Clonazepam	523
Clorazepate Dipotassium	130
Delorazepam	1,040
Desalkylflurazepam	260
Diazepam	130
Estazolam	1,670
Flunitrazepam	257
(±) Lorazepam	1,040
RS-Lorazepam glucuronide	107
Midazolam	8,340
Nitrazepam	63
Norchlordiazepoxide	134
Nordiazepam	260

Oxazepam	200
Temazepam	67
Triazolam	1,670
BUPRENORPHINE (BUP 10)	
Buprenorphine	10
Norbuprenorphine	20
BUPRENORPHINE (BUP 5)	
Buprenorphine	5
Norbuprenorphine	10
COCAINE (COC 300)	
Benzoylcegonine	300
Cocaethylene	300
Cocaine	300
Metoclopramide	80,000
Procaine	75,000
COCAINE (COC 150)	
Benzoylcegonine	150
Cocaethylene	2,500
Cocaine	1000
MARIJUANA (THC 50)	
11-nor- $\Delta^8$ -THC-9-COOH	50
11-Hydroxy- $\Delta^8$ -Tetrahydrocannabinol	5,000
11-Nor- $\Delta^8$ -THC-9-COOH	50
11-Nor- $\Delta^8$ -Tetrahydrocannabinol-9 Carboxylic Glucuronide	2,500
$\Delta^8$ -THC	20,000
$\Delta^9$ -THC	20,000
MARIJUANA (THC 20)	
11-nor- $\Delta^8$ -THC-9-COOH	20
11-nor- $\Delta^8$ -THC-9-COOH	50
Cannabinol	15,000
$\Delta^8$ -THC	10,000
$\Delta^9$ -THC	10,000
MARIJUANA (THC 15)	
11-nor- $\Delta^8$ -THC-9-COOH	15
11-Hydroxy- $\Delta^8$ -Tetrahydrocannabinol	5,000
$\Delta^8$ -THC	3,000
$\Delta^9$ -THC	2,000
Cannabinol	> 100,000
Cannabidiol	> 100,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE (mAMP 1000)	
(+/-)-3,4-Methylenedioxy-n-ethylamphetamine	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/-methamphetamine	1,000
+methamphetamine	1,000
Ranitidine (Zantac)	50,000
Methylenedioxymethamphetamine	2,500

METHAMPHETAMINE (mAMP 500)	
d-methamphetamine	500
D,l-Methamphetamine	1,000
l-Ranitidine	500,000
Procaine	200,000
(+/-)-Methylenedioxyamphetamine	90,000
Methylenedioxymethamphetamine	2,500
(+/-)-3,4-Methylenedioxy-n-ethylamphetamine	10,000
METHAMPHETAMINE (mAMP 300)	
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine	6,000
Procaine (Novocaine)	18,000
Trimethobenzamide	6,000
+/-methamphetamine	300
+methamphetamine	300
Ranitidine (Zantac)	15,000
(+/-) 3,4-Methylenedioxymethamphetamine	750
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
Methylenedioxymethamphetamine	500
3,4-Methylenedioxyamphetamine	3,000
(+/-)-3,4-Methylenedioxy-n-ethylamphetamine	300
OPIATE (OPI 300, MOP, MOR)	
6-acetylmorphine	500
Codeine	100
Eserine (Physostigmine)	15,000
Ethylmorphine	100
Heroin	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine	300
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000
OPIATE (OPI 2000)	
6-acetylmorphine	1,000
Codeine	800
Ethylmorphine	400
Heroin	10,000
Hydromorphone	2,000
Hydrocodone	5,000
Morphine	2,000
Morphine-3-glucuronide	1,000
Oxycodone	50,000
Thebaine	26,000
OXYCODONE (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1,580
Hydromorphone	12,500
Oxymorphone	1,580

Thebaine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4 Hydroxy PCP	90
PCP Morpholine	625
PREGABALIN (PGB)	
Pregabalin	2000
PROPOXYPHENE (PPX)	
Norpropoxyphene	300
Propoxyphene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Amitriptyline	5,000
Clomipramine	12,500
Desipramine	200
Doxepin	2,000
Imipramine	400
Maprotiline	2,000
Nordoxepin	1,000
Promazine	1,500
Promethazine	2,500
Trimipramine	3,000
2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHELYLPYRROLIDINE (EDDP 300)	
EDDP	300
Phencyclidine	50,000
Disopyramide	50,000
Mianserin	100,000
Tramadol	100,000
Venlafaxine hydrochloride	100,000
2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHELYLPYRROLIDINE (EDDP 100)	
EDDP	100
Disopyramide	15,000
Mianserin	25,000
Tramadol	60,000
Venlafaxine hydrochloride	30,000
6-ACETYLMORPHINE (6-ACM)	
6-Acetylmorphine	10
Morphine	40
Bilirubin	3,500
Codeine	10
Diacetylmorphine	50
Ethylmorphine	24
Hydrocodone	100
Hydromorphone	100
Levorphanol	400
Morphine-3- $\beta$ -D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500



Norcodeine	15,000
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
COTININE (COT)	
(-)-Cotinine	200
(-)-Nicotine	6,250
SYNTHETIC CANNABINOID (K2)	
JWH-018 5-pentanoic acid metabolite	20
JWH-073 4-butanoic acid metabolite	20
MAM2201 N-pentanoic acid metabolite	200
JWH-398 N-pentanoic acid metabolite	400
JWH-210 N-(5-carboxypentyl) metabolite	2,500
JWH-073 3-hydroxybutyl metabolite	2,500
JWH-018 N-4-hydroxypropyl	8,000
JWH-073 4-hydroxybutyl metabolite	40,000
JWH-019 5-hydroxyhexyl metabolite	40,000
JWH-018 5-hydroxypentyl metabolite	45,000
JWH-122 5-hydroxypentyl metabolite	50,000
JWH-122 4-hydroxypentyl metabolite	50,000
JWH-019 6-hydroxyhexyl metabolite	50,000
RCS-4 N-(5-carboxypentyl) metabolite	50,000
Trifluoperazine dihydrochloride	50,000
Trifluoperazine hydrochloride	70,000
2,4,6-Trimethylbenzamide	100,000
AB-PINACA (K3)	
AB-Pinaca 5-Pentanoic Acid	10
AB-FUBINACA	200
AB-Pinaca	100
AB-Pinaca 4-Hydroxypentyl Metabolite	15
AB-Pinaca 5-Hydroxypentyl Metabolite	15
AB-Pinaca 5-Pentanoic Acid Metabolite	10
ADB-Pinaca 5-Pentanoic Acid Metabolite	25
UR-144	Negative at 10,000
UR-144 5- Hydroxypentyl Metabolite	Negative at 10,000
UR-144 5- Pentanoic Acid Metabolite	Negative at 10,000
APinaca 5- Hydroxypentyl Metabolite	Negative at 10,000
UR-144 (K4)	
UR-144 5-Pentanoic Acid	25
UR-144 5-Hydroxypentyl Metabolite	300
UR-144	Negative at 10,000
AB-FUBINACA	Negative at 10,000
AB-Pinaca	Negative at 10,000
AB-Pinaca 4-Hydroxypentyl Metabolite	Negative at 10,000
AB-Pinaca 5-Hydroxypentyl Metabolite	Negative at 10,000
AB-Pinaca 5-Pentanoic Acid Metabolite	Negative at 10,000
APinaca 5- Hydroxypentyl Metabolite	Negative at 10,000
ADB-Pinaca 5-Pentanoic Acid Metabolite	Negative at 10,000
KETAMINE (KET)	
Ketamine	1,000
Methadone	100,000

Meperidine	30,000
Methamphetamine	40,000
Methoxyphenamine	20,000
D-methamphetamine	40,000
Promethazine	50,000
Phencyclidine	10,000
Bupivacaine	20,000
Disopyramide	100,000
Eserine	70,000
Glutathione reduced	50,000
Mianserin	30,000
Naphazoline hydrochloride	20,000
Nomifensine	100,000
Prilocaine	50,000
Promazine	100,000
Pyrilamine	50,000
Thioridazine hydrochloride	100,000
Benzthiazide	100,000
Picrotoxin	10,000
Phenyltoloxamine	100,000
2,4,6-Trimethylbenzamide	100,000
KRATOM (KRA)	
Mitragynine	100
7-Hydroxymitragynine	Negative at 10,000
FENTANYL (FEN 10)	
Fentanyl	10
TRAMADOL (TRA 50)	
Tramadol	50
TRAMADOL (TRA 100)	
Tramadol	100
METHYLENEDIOXYPYROVALERONE (MDPV)	
Methylenedioxypropylvalerone	1,000
Butylone	1,000
Ethylone	1,000
Methylone	10,000
Mephedrone	10,000
Methedrone	10,000
Pyrovalerone	4,000
Naphyrone	>100,000
Flephedrone	>100,000
Brompheniramine	>100,000
Methyprylon	>100,000
Zomepirac	>100,000
ETHYL GLUCURONIDE (ETG 300)	
Ethyl-β-D-glucuronide	300

ETHYL GLUCURONIDE (ETG 500)	
Ethyl-β-D-glucuronide	500

The following substances may interfere with the alcohol test: strong oxidizers, ascorbic acid, tannic acid, polyphenolic compounds, mercaptans, uric acid, bilirubin, oxalic acid and so on, but these compounds are not normally present in sufficient amount in urine to interfere with the test.

EFFECT OF URINARY SPECIFIC GRAVITY

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.03) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **ECO II CUP® One Step Drug Test** was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

EFFECT OF THE URINARY PH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **ECO II CUP® One Step Drug Test**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

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