MATRIX Drugs of Abuse/Alcohol Panel Test

Plus Optional Adulterant Strip(s)

FOR THE QUALITATIVE ASSESSMENT OF DRUGS AND/OR THEIR METABOLITES IN HUMAN URINE
and
URINE ALCOHOL (Optional)
For THE SEMI-QUANTITATIVE ASSESSMENT OF ETHYL ALCOHOL IN HUMAN URINE
Plus
URINE CHECK (Optional)
For THE VALIDATION OF URINE SPECIMEN EXAMINED

For in vitro Diagnostic and Forensic Use

Drugs of Abuse/Alcohol (DOA/ALC) Panel Test Device

Matrix Drugs of Abuse/Alcohol Panel Test

Optional: Alcohol & Adulteration

REF

Urine Alcohol Strip can be optionally integrated into DOA/Alcohol Panel Test Device.
Urine check adulteration strip can also be optionally integrated into both DOA/Alcohol Panel Test Devices with custom parameters. pH and/or creatinine are the optional standard parameters whereas five other parameters are offered as options for custom made test devices. The currently available Adulteration parameters offered by Matrix Diagnostics Ltd. are Creatinine, pH, Specific Gravity, Nitrite, Oxidants, Glutaraldehyde, Bleach, and Pyridinium Chlorochromate.

INTENDED USE

Matrix DOA/Alcohol Panel Test and Matrix DOA/Alcohol Panel Test Card, hereinafter referred to as DOA/Alcohol Panel Test Device, is an immunochromatography based one step in vitro test. It is designed for qualitative determination of illicit drugs and their metabolites in human urine specimens. This assay may be used in the point of care setting. Below is a list of cut-off concentrations for each drug.

Amphetamine	1000	ng/ml of d-amphetamine
Barbiturate	300	ng/ml of secobarbital
Benzodiazepine	300	ng/ml of oxazepam
Buprenorphine	10	ng/ml of Buprenorphine-3-β-d-glucuronide
Cocaine	300	ng/ml of benzoylecgonine
EDDP	100	ng/ml of EDDP
Ketamine	1000	ng/ml of Ketamine
Methadone	300	ng/ml of methadone
Methamphetamine (includes Ecstasy)	1000	ng/ml of (+)methamphetamine
MDMA (Ecstasy specific)	500	ng/ml of MDMA
Opiate*	300	ng/ml of morphine
Opiate II*	2000	ng/ml of morphine
Oxycodone	100	ng/ml of oxycodone
Phencyclidine	25	ng/ml of phencyclidine
Cannabinoid (THC)	50	ng/ml of 11-nor-Δ^9-THC-9-COOH
Propoxyphene	300	ng/ml of Norpropoxyphene
Tramadol	200	ng/ml of Tramadol
Tricyclic antidepressant (TCA)	1000	ng/ml of Nortriptyline
6-MAM	10	ng/ml of 6-Acetylmorphine
ZOL	50	ng/ml of Zolpidem Phenyl-4-carboxylic acid
LSD	20	ng/ml of Lysergic acid diethylamide
7-ACL	300	ng/ml of 7-Aminoclonazepam
PGB	500	ng/ml of Pregabalin
MES	300	ng/ml of Mescaline
MDPV	500	ng/ml of 3,4-Methylenedioxypyrovalerone
MCAT	500	ng/ml of Methcathinone
MEP	500	ng/ml of Mephedrone
GAB	2000	ng/ml of Gabapentin
ETG	500	ng/ml of Ethyl Glucuronide
ETG II*	1000	ng/ml of Ethyl Glucuronide
CFYL	500	ng/ml of Carfentanil
K2-AB	25	ng/ml of AB-PINACA
CAF	8000	ng/ml of Caffeine
K2	50	ng/ml of JHW-018 and JWH-073
FYL	10	ng/ml of Fentanyl
COT	200	ng/ml of Cotinine
MQL	300	ng/ml Methaqualone
Alcohol	40	mg/dl (0.04% BAC) of Alcohol
Oxidants/ Specific Gravity / pH/Nitrite / Glutaraldehyde/Creatinine		

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated. The optional built-in Adulteration Test is for validation of urine specimen's integrity and must not be used for In Vitro diagnostic use.

* ***SAMHSA recommends a cut-off concentration of 2000 ng/ml for Opiate Test***

SUMMARY AND EXPLANATION

Drugs of Abuse

Amphetamines are a class of potent sympathominetic agents with therapeutic applications. The most common amphetamines are d-amphetamine and d, l-amphetamine. Amphetamines are central nervous stimulants that cause the neurotransmitters epinephrine, norepinephrine and dopamine to be released into the brain and body giving users feelings of euphoria, alertness, and increased energy. Chronic abuse of amphetamine leads to tolerance and drug reinforcement effect. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations and psychotic behavior. Amphetamine is metabolised by a number of pathways. In general, acid urine promotes excretion whereas alkaline urine retards it. In 24 hours, approximately 79% of the amphetamine dose is excreted in acid urine and about 45% in alkaline urine. Typically, about 20% is excreted as unchanged amphetamine. Unchanged amphetamine can be detected up to 1 –2 days after use.

Barbiturates are a group of prescription drugs that are frequently abused. They can depress the central nervous system. Acute higher dose induces exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effects of short-acting barbiturates, such as secobarbital last 3 to 6 hours. The effects of long-acting barbiturates such as phenobarbital last 10 to 20 hours. Short-acting barbiturates normally remain detectable in urine for 4 to 6 days, while long-acting barbiturates can be detected for up to 30 days. Barbiturates are excreted in the urine in unchanged forms, hydroxylated derivatives, carboxylated derivatives and glucuronide conjugates.

Benzodiazepines are a class of widely prescribed central nervous system depressants which have anxiolytic, hypnotic, anticonvulsant and muscle relaxant effects. Chronic abuse can result in addiction and tardive dyskinnesia. Acute higher doses lead to drowsiness, dizziness, muscle relaxation, lethargy, coma and possible death. The effects of benzodiazepines use last 4 – 8 hours. Many of the benzodiazepines share a common metabolic route and are excreted as oxazepam and its glucuronide in urine. Oxazepam is detectable in the urine for up to 7 days after drug use.

Buprenorphine a derivative of the baine, is an opioid that has been marketed in the United States as the Schedule V parenteral analgesic Buprenex. In 2003, based on a reevaluation of available evidence regarding the potential for abuse, addiction, and side effects, DEA reclassified buprenorphine from a Schedule V to a Schedule III narcotic. Buprenorphine resembles morphine structurally but has a longer duration of action than morphine and can be administrated sublingually as an analgesic. In October 2002, FDA approved the use of a buprenorphine monotherapy product, Subutex, and a buprenorphine/naloxone combination product, Suboxone, for the treatment of opioid addiction. Subutex and Suboxone are the first narcotic drugs available under the US Drug Act (DATA) of 2003 for the treatment of opiate dependence that can be prescribed in the US in a physician's work place. It has also been shown that buprenorphine has abuse potential and may itself cause dependency. In addition, a number of deaths have been recorded as a result of overdose with intravenously injected buprenorphine in conjunction with other psychotropic drugs such as benzodiazepines. Buprenorphine is metabolised primarily by n-dealkylation to form glucuronide-buprenorphine and glucuronide-norbuprenorphine.

Cocaine derived from the leaves of cocoa plant, is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological effects induced by cocaine are: euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of cocaine could induce tolerances and physiological dependency which leads to its abuse. Cocaine is used by smoking, intravenous, intransal or oral administration and excreted in the urine primarily as benzoylecgonine in a short period. Benzoylecgonine has a biological half-life of 5 – 8 hours, which is much longer than that of cocaine (0.5 – 1.5 hours), and can be generally detected for 12 – 72 hours after cocaine use or exposure.

EDDP 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine, is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate dependant patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The detection of EDDP is more beneficial than traditional methadone screening, because EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

Methadone is a synthetic opioid, clinically available. It is used clinically for the treatment of severe pain and in maintenance programs for morphine and heroine addicts. Methadone acts on the central nervous and cardiovascular systems to produce respiratory and circulatory depression. Methadone also produces miosis and increases the tone of smooth muscle in the lower gastrointestinal tract while decreasing the amplitude of contractions. Acute higher doses induce analgesia, sedation, respiratory depression and coma. After methadone administration, the major urinary excretion products are methadone and its metabolites, EDDP and EMDP. Large individual variations in the urine excretion of methadone are output of methadone from 5-22%. Typically, following a 5 mg oral dose, methadone and EDDP account for 5% of the dose in the 24-hour urine. In those individuals on maintenance therapy, methadone may account for 5 to 50% of the dose in the 24-hour urine and EDDP may account for 3 to 25% of the dose.

Methamphetamine is the most popular synthetic derivative of the amphetamines. It is a potent sympathomimetic agent with therapeutic applications. Acute large doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. More acute response produces anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in the urine as amphetamine and oxized and deaminated derivatives. However, 10-40% of methamphetamine is excreted unchanged. Methamphetamine is generally detectable in the urine for 3 to 5 days after use.

MDMA Methylenedioxymethamphetamine (**E**cstasy) is a designer drug first synthesised 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. The most pervasive effect of MDMA, occurring in almost all people who have taken a reasonable dose of the drug, is to produce a clenching of the jaws.

Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and human anaesthetic. Certain doses of ketamine can cause dream-like states and hallucinations. In high doses, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolised in the liver and excreted through the kidney. The half-life of ketamine in the body is around three hours.

Opiate Opioid analgesics comprise of a large group of substances that control pain by depressing the central nervous system. Acute high dose used by abusers or addicts can cause depressed coordination, disrupted decision, decreased respiration, hypothermia and coma. Morphine is excreted unmetabolised and is the marker metabolic product of opiates. Morphine and morphine glucuronide is detectable in urine for several days after an opiate dose.

Oxycodone is known as Oxycontin, Roxicodone and is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiate derived from opium. Like other opiates, oxycodone is characterised by its analgestic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and stripiac arrest. Oxycodone is metabolised by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free oxycodone, 7-29% glucuronide conjugated oxycodone, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection

time window of oxycodone is 1-3 days following use.

Phencyclidine commonly known as PCP, is a hallucinogen which interacts with dopamine, cholinergic and adrenergic systems. It has dose dependent stimulant, depressant, hallucinogenic and psychological effects. PCP is mostly administered by oral or intravenously. Even a moderate amount of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high does, from 100 to 500 ng/ml, PCP can cause convulsions, hypertion, prolonged coma, absent peripheral sensation, and even death. PCP is metabolised via hydroxylation, oxidation, and conjugation with glucuronic acid in the liver. About 10% of the does is excreted in urine as unchanged drug. For chronic users, PCP can be detected in the urine for 7 to 8 days after drug administration.

Propoxyphene is a prescription drug for the relief of pain. Although slightly less selective than morphine, Propoxyphene binds primarily to opioid receptors and produces analgesia and other CNS effects that are similar to those seen with morphine-like opioids. It is likely that at equianalgesic doses the incidence of side effects such as nausea, anorexia, constipation, abdominal pain, and drowsiness are similar to those of codeine. After oral administration, concentrations of Propoxyphene in plasma reach their highest values at 1 to 2 hours. There is great variability between subjects in the rate of clearance and the plasma concentrations that are achieved. The percentage of excreted unchanged Propoxyphene in urine is less than 1%. In humans, the major route of metabolism is N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent Propoxyphene (6 to 12 hours), and its accumulation with repeated doses may be responsible for some of the observed toxicity.

THC The agents of Marijuana that cause various biological effects in humans are called cannabinoids. Cannabinoid is a central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, and produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of cannabinoids could cause the development of tolerances and physiological dependency and lead to abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. Δ^9-THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor-Δ^9-THC-9-COOH, which are found within hours of exposure and remain detectable in the urine for 3-10 days after smoking.

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 metabolised after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver.

TCA Tricyclic antidepressants, commonly known as TCA, are a group of antidepressant drugs. TCA are mostly administered by oral or intramascularly. The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures and EKG changes. Nortriptyline, Desipramine (Pertofran) and Imipramine (Tofranil) are the most often used TCA. TCA's half life varies from a few hours to a few days. TCA's are excreted with less than 1% of the unchanged drug.

6-MAM 6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM).6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-MAM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on 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 sulfate, and heroin. 6-MAM 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-MAM guarantees that heroin was in fact used as recently as within the last day. 6-MAM is naturally found in the brain, but in such small quantities that detection of this compound in urine virtually guarantees that heroin has recently been consumed.

ZOL Zolpidem is a prescription medication used for the treatment of insomnia and some brain disorders. It is a short-acting nonbenzodiazepine hypnotic of the imidazopyridine class that potentiates GABA, an inhibitory neurotransmitter, by binding to $GABA_A$ receptors at the same location as benzodiazepines. It works quickly, usually within 15 minutes, and has a short half-life of two to three hours. Zolpidem has not adequately demonstrated effectiveness in maintaining sleep, unless delivered in a controlled-release (CR) form. However, it is effective in initiating sleep. Its hypnotic effects are similar to those of the benzodiazepine class of drugs, but it is molecularly distinct from the classical benzodiazepine molecule and is classified as an imidazopyridine. Flumazenil, a benzodiazepine receptor antagonist, which is used for benzodiazepine overdose, can also reverse zolpidem's sedative/hypnotic and memory-impairing effects.

LSD Lysergic acid diethylamide, abbreviated LSD or LSD-25, also known as lysergide and colloquially as acid, is a semisynthetic psychedelic drug of the ergoline family, well known for its psychological effects which can include altered thinking processes, closed and open eye visuals, synaesthesia, an altered sense of time and spiritual experiences, as well as for its key role in 1960s counterculture. It is used mainly as an entheogen, recreational drug, and as an agent in psychedelic therapy. LSD is non-addictive, is not known to cause brain damage, and has extremely low toxicity relative to dose, although in rare cases adverse psychiatric reactions such as anxiety or delusions are possible.

7-ACL 7-aminoclonazepam is the major metabolite of clonazepam. Clonazepam sold under the brandname Klonopin among others, is a medication used to prevent and treat seizures, panic disorder, and for the movement disorder known as akathisia. It is a type of benzodiazepine. As a major metabolite, 7-aminoclonazepam may be used to monitor use of the parent drug, clonazepam. Clonazepam, marketed as Klonopin and Rivotril, is a long-acting benzodiazepine with anxiolytic, anticonvulsant, muscle relaxant, and hypnotic properties.

PGB Pregabalin is a medication primarily used for epilepsy, neuropathic pain, and fibromyalgia. Its use for epilepsy is as an add-on therapy for partial seizures with or without secondary generalization in adults. It is also considered useful for generalized anxiety disorder.Pregabalin is a lipophilic structural analogue of γ-Aminobutyric acid (GABA) and classified as a depressant by the Drug Enforcement Agency. It is a neurotransmitter modulator that has analgesic, anticonvulsant, anxiolytic, and sleep-modulating properties.Pregabalin is a potent gabapentinoid and a close structural analogue of GABOB (β-hydroxy-GABA), baclofen (β-(4-chlorophenyl)-GABA),and phenibut (β-phenyl-GABA). Common side effects include dizziness, sleepiness, confusion, trouble with memory, poor coordination, dry mouth, problem with vision, and weight gain. Potentially serious side effects include angioedema, drug misuse, and an increasedsuicide risk.

MES Mescaline or 3,4,5-trimethoxyphenethylamine is a naturally occurring psychedelic alkaloid of the phenethylamineclass, known for its hallucinogenic effects similar to those of LSD and psilocybin. It shares strong structural similarities with the catecholamine dopamine.It occurs naturally in the peyote cactus (Lophophora williamsii), the San Pedro cactus (Echinopsis pachanoi) and in the Peruvian torch (Echinopsis peruviana), and as well in a number of other members of the Cactaceae plant family. It is also found in small amounts in certain members of the Fabaceae (bean) family, including Acacia berlandieri. Tolerance builds with repeated usage, lasting for a few days. Mescaline causes cross-tolerance with other serotergic psychedelics such as LSD andpsilocybin. About half the initial dosage is excreted after 6 hours, but some studies suggest that it is not metabolized at all before excretion. Mescaline appears to not be subject to metabolism by CYP2D6and between 20% and 50% of mescaline is excreted in the urine unchanged, and the rest being excreted as the carboxylic acid form of mescaline, a likely result of MAO degradation.

MDPV Methylenedioxypyrovalerone (MDPV) is a psychoactive drug with stimulant properties which acts as a norepinephrine-dopamine reuptake inhibitor. The primary psychological effects have a duration of roughly 3 to 4 hours, with after effects such as tachycardia, hypertension, and mild stimulation lasting from 6 to 8 hours.

MCAT Methcathinone, is a monoamine alkaloid and psychoactive of stimulant, a substituted cathinone. Methcathinone is a highly addictive drug, primarily psychologically addicting and the degree of addiction to the drug are emotional or psychological. It has been popularized and continues to be sold under misleading names such as "bath salts", "plant fertilizers" or "research chemicals", but it is actually a powerful psycho-stimulant used as a recreational drug. Effects of this drug typically last from 4 to 6 hours. It is used as a recreational drug due to its potent stimulant and euphoric effects and is considered to be addictive, with both physical and psychological withdrawal occurring if its use is discontinued after prolonged or high-dosage administration . It is usually snorted, but can be smoked, injected, or taken orally. Methcathinone is listed as a Schedule I controlled substance by the Convention on Psychotropic Substances and the United States' Controlled Substances Act, and as such it is not considered to be safe or effective in the treatment, diagnosis, prevention, or cure of any disease, and has no approved medical use. Methcathinone has very strong affinities for the dopamine transporter and the norepinephrine (noradrenaline) transporter. Its affinity for the serotonin transporter is less than that of methamphetamine.

MEP Mephedrone, also known as 4-methylmethcathinone (4-MMC) or 4-methylephedrone is a synthetic stimulant drug of the amphetamine and cathinone classes. Slang names include drone, M-CAT, White Magic and meow meow. It is chemically similar to the cathinone compounds found in the khat plant of eastern Africa. Mephedrone comes in the form of tablets or a powder, which users can swallow, snort or inject, producing similar effects to MDMA, amphetamines and cocaine. In addition to its stimulant effects, Mephedrone produces side effects, of which teeth grinding are the most common. A number of metabolites are possible, however the n-demethyl metabolite of Mephedrone will be 4-Methylcathinone. This metabolite appears to be nearly inactive as a Monoamine Oxydase Inhibitor .On further metabolism of this metabolite one of the possible metabolites is 4-Methylnorephedrine, caused by the reduction of the Keto.A dose of 150mg-250mg is the average, giving a duration of around 2 hours.the duration will lengthen in larger 250mg+ dosages .

GAB Gabapentin (GAB) marketed under the brand name Neurontin among others, is a medication used to treat epilepsy,neuropathic pain, hot flashes, and restless leg syndrome. In epilepsy it may be used for those with partial seizures. It is recommended as one of a number of first line medications for the treatment of neuropathic pain indiabetic neuropathy, post-herpetic neuralgia, and central neuropathic pain. The mechanism of the anticonvulsant action of gabapentin has not been fully described. Several possible mechanisms for pain improvement have been discussed. Though similar in structure to the endogenous neurotransmitter GABA, gabapentin has not been shown to bind to GABA receptors at concentrations at or below 1 mM. Gabapentin modulates the action of glutamate decarboxylase (GAD) and branched chain aminotransferase (BCAT), two enzymes involved in GABA biosynthesis. In human and rat studies, gabapentin was found to increase GABA biosynthesis, and to increase non-synaptic GABA neurotransmission in vitro.Common side effects include sleepiness and dizziness. Serious side effects may include an increased risk of suicide, aggressive behaviour, and drug reaction with eosinophilia and systemic symptoms. It is unclear if it is safe duringpregnancy or breastfeeding. Lower doses should be used in people with kidney problems. Gabapentin affects the inhibitory neurotransmitter γ-aminobutyric acid (GABA).

CFYL Carfentanyl is an analog of the synthetic opioid analgesic fentanyl. It is 10,000 times more potent than morphine, making it among the most potent commercially used opioids. Carfentanil was first synthesized in 1974. It is marketed under the trade name Wildnil as a general anaesthetic agent for large animals. Side effects of carfentanil are similar to those of fentanyl, which include itching, nausea and respiratory depression, which can be life-threatening. Carfentanil is classified as Schedule II under the Controlled Substances Act in the United States with a DEA ACSCN of 9743.

K2-AB AB-PINACA is a synthetic cannabinoid usually sold as a herbal smoking mixture designed to mimic THC, the active chemical of cannabis. Synthetic cannabinoids are classed as 'New Psychoactive Substances' (NPS) which are unregulated substances that have become newly available on the market as an alternative to illegal drugs. As a reaction to prohibition, synthetic cannabinoid producers change the compounds found in designer drugs and create new generations of synthetic drugs, such as AB-PINACA. As a result, accidental overdose and severe psychiatric complications may be more likely to occur because the type and amount of active compound may vary considerably from batch to batch. Other effects may include agitation, rapid heart rate, confusion, dizziness and nausea.

CAF Caffeine is a central nervous system (CNS) stimulant of the methylxanthine class. It is the world's most widely consumed psychoactive drug. It is found in the seeds, nuts, or leaves of a number of plants native to South America and East Asia and confers on them several survival and reproductive benefits. Caffeine can produce a mild form of drug dependence-associated with withdrawal symptoms such as sleepiness, headache, and irritability – when an individual stops using caffeine after repeated daily intake. After intravenous administration of caffeine the urine level of the drug is approximately the same in each of the first 4 hourly specimens. Blood samples taken 10 and 70 minutes after injection of the drug were analyzed and showed 0.29 and 0.28mg. per 100 cc. respectively. There are to be contrasted with the 1st hour urine which contained 0.73mg.per 100 cc., essentially 3 times that in the blood. After oral administration of caffeine to the horse the concentration of caffeine in the urine rose progressively during the first 3 hours, remained relatively constant through the 8th hours. At 48 hours, a urine specimen contained approximately 0.17mg. per 100 cc. of caffeine. In addition, flu-like symptoms, nausea/vomiting, and muscle pain/stiffness were judged likely to represent valid symptom categories. In experimental studies, the incidence of headache was 50% and the incidence of clinically significant distress or functional impairment was 13%. Typically, onset of symptoms occurred 12–24 h after abstinence, with peak intensity at 20–51 h, and for a duration of 2–9 days. 1% to 3% of caffeine is excreted unchanged in the urine. The rate of caffeine metabolism is variable, with a half-life of 4 to 6h.

ETG 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 glucuronosyl transferase.ETG is a product of metabolic process about of Ingested alcohol (ethanol) rapidly metabolized in the body, which is excreted in the blood, hair and urine. By using The ETG Rapid Test Device (Urine), can detect ETG 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 rehabilitation programs

K2 Synthetic cannabis is a psychoactive designer drug derived from natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic cannabis product. Studies suggest that synthetic cannabinoid intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness. When synthetic cannabis blends first went on sale in the early 2000s (decade), it was thought that they achieved an effect through a mixture of legal herbs. Laboratory analysis in 2008 showed that this is not the case, and that they in fact contain synthetic cannabinoids that act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. A large and complex variety of synthetic cannabinoids, most often cannabicyclohexanol, JWH-018, JWH-073, or HU-210, are used in an attempt to avoid the laws that make cannabis illegal, making synthetic cannabis a designer drug. It has been sold under various brand names, online, in head shops, and at some gas stations.

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%. 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. 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.

FYL Fentanyl is a synthetic opioid related to the phenylpiperidines.Fentanyl is approximately 100 times more potent than morphine. This agent is highly lipid soluble and rapidly cross the blood-brain barrier. This is reflected in the half-life for equilibration between the plasma and cerebrospinal fluid of approximately 5 minutes for fentanyl. The levels in plasma and cerebrospinal fluid decline rapidly owing to redistribution of fentanyl from highly perfused tissue groups to other tissues, such as muscle and fat. As saturation of less well-perfused tissue occurs, the duration of effect of fentanyl and sufentanil approaches the length of their elimination half-lives of between 3 and 4 hours. Fentanyl undergoes hepatic metabolism and renal excretion. Therefore, with the use of higher doses or prolonged infusions, fentanyl becomes longer acting.

MQL Methaqualone is classified as a sedative/hypnotic. It was originally synthesized in India to combat malaria but found to be ineffective. Methaqualone did prove effective as a sedative and was developed in the hopes of avoiding some of the adverse effects of the barbiturates, particularly their high capacity for addiction. Unfortunately, methaqualone was found to be just as addictive. Psysiologically, methaqualone is cumulative and tolerance occurs rapidly in some individuals. In addition, it is extensively metabolized,at least 12 hydroxylated metabolites having been identified in the urine. The major metabolites are methaqualone-N-oxide, conjugate 4'-hydroxy-methaqualone,conjugated 2-hydroxymethaqualone.About 0.2% of methaqualone is excreted unchanged within 24 hours;40-50% of the methaqualone is excreted as metabolites within 72 hours,mostly as the glucuronide conjugates. The half-life for methaqualone averages 33 to 36 hours.It can be detected up to four days after administration.Side effects from chronic use of methaqualone are loss of motor coordination,walking into walls,ataxia,slurred speech,drowsiness and nystagmus.Severe acute overdose tends to produce muscle spasms, abnormally rapid reflexes,extreme muscle tension and restlessness.

Alcohol Acute alcohol intoxication can lead to loss of alertness, coma, and even death. Long term effects include internal organ damage and birth defects. The blood alcohol concentration (BAC) at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine is set at 0.04%.

UrineCheck: Adulteration Test(s)

UrineCheck adulteration tests are built-in firm plastic strips to which options of one (1) up to six (6) different reagent areas can be affixed. UrineCheck test(s) is/are read-to-use and disposable. No equipment is required for its use. Only fresh and uncentrifuged urine samples without preservatives are to be used.

UrineCheck provides tests for Creatinine, pH, Specific Gravity, Nitrite, Oxidants, Glutaraldehyde, Bleach, and Pyridinium Chlorochromate in urine. Test results may be useful for assessing the integrity of the urine sample while running Drugs-of-Abuse & Alcohol testing, for example, whether the sample is possibly diluted with water or other liquids as indicated by the Creatinine and specific gravity tests. UrineCheck detects whether the sample contains commercially available adulterants including nitrite, Glutaraldehyde, and other oxidizing agents. UrineCheck can also assess whether the sample is possibly contaminated by acidic (vinegar) or basic (ammonia solution) adulterants as indicated by the pH test.

PRINCIPLE

Drugs of Abuse

Each component strip of the DOA/Alcohol Panel Test Device is based on the principle of specific immunochemical reaction between antibodies and antigen to analyse particular compounds in human urine specimens. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a coloured band on the test line zone, indicating a positive result, while the presence of a coloured band indicates a negative result.

A control line is present in the test window to work as procedural control. This coloured band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

Alcohol

Alcohol Test is based on the high specifity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

$$EtOH + TMB \xrightarrow{ALOx/Peroxidase} CH_3CHO + Colored\ TMB$$

The distinct colour on reactive pad could be observed in less than 20 seconds after the urine samples migrates over the reaction pad 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 colour on the reactive pad. However, these alcohols are not normally present in urine.

UrineCheck: Adulteration Test(s)

In general, all UrineCheck Tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample affecting colour changes. Results are obtained by comparing the colour on each of the test pads with the corresponding pad on the colour chart provided.

Creatinine: Testing for sample dilution. In this assay, Creatinine reacts with a Creatinine indicator in an alkaline condition to form a purplish- brown colour complex. The concentration of Creatinine is directly proportional to the colour intensity of the test pad.

Specific Gravity: Testing for sample dilution. This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, the colours range from dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

pH: Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colours over wide pH range. The colours range from orange (low pH) to yellow and green to blue (high pH).

Nitrite: Testing for the presence of exogenous nitrite. Nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink-red/purple colour.

Oxidants: Testing for presence of oxidizing reagents. In this reaction, a colour indicator reacts with oxidants such as hydrogen peroxide, ferricyanide, persulfate, or pyridinium chlorochromate to form a blue colour complex. Other colours may indicate the presence of other oxidants.

Glutaraldehyde: Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the Glutaraldehyde reacts with an indicator to form a pink/purple colour complex.

Bleach: Testing for the presence of bleach in urine. In this test, the presence of bleach forms a blue-green, brown, or orange colour complex.

Pyridinium Chlorochromate: Testing for the presence of Pyridinium Chlorochromate in urine. In this test, the presence of chromate forms a blue-green colour complex.

MATERIALS PROVIDED

1. ***Instructions for use***
2. ***One Drugs* of DOA/Alcohol Panel Test Device *(with optional Alcohol and /or Adulteration Test)***
   Drugs Of Abuse
   The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for antibody.

   Test zone: contains antigen conjugates
   Control zone: contains antibody
   Conjugate pad: contains antibody.

   Alcohol *(optional)*
   Each Alcohol test contains these materials:

Tetramethylbenzidine (TMB)	0.12 mg
Alcohol oxidase (EC)	0.5 IU
Peroxidase(EC)9	35 IU
Proteins	0.15mg

   Adulteration Test *(optional)*
3. ***Alcohol /Adulteration Test Colour Chart*** *(When order Alcohol and/or Adulteration Tests)*

MATERIAL REQUIRED BUT NOT PROVIDED

1. ***Urine collection container.***
2. ***Timer or clock.***

STORAGE AND STABILITY

The DOA/Alcohol Panel Test Device should be stored at 2 to 30°C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being opened. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product. Do not open foil pouch until test is ready to be used.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8°C or frozen for up to 7 days. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 50% above and below cutoff concentration. If control values do not fall within established range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

Drugs of Abuse

The DOA Panel Test Device provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Alcohol

Alcohol test may be qualitatively verified by using a test solution prepared by adding 0.75 ml of ethanol alcohol into 240 ml of distilled water or negative urine control. This solution should show a distinct positive result.

UrineCheck: Adulteration Test(s)

For best results, performance of UrineCheck test should be confirmed by testing known negative and positive specimens.

PROCEDURE

1

Bring all materials and specimens to room temperature.

2

Remove the DOA/Alcohol Panel Test Device from sealed foil pouch.

3 (For Panel Test Card Only)

Place the Panel Test Card on a flat surface and label the device with patient ID.

4

Place the sample pad end into the urine specimen. Use care to hold each pad in the urine without touching the plastic card.

5

DOA/Alcohol Panel Test with no Alcohol nor Adulteration Tests

Hold the device in the urine until a reddish colour appears at the test area (approximately 20 seconds)*.	Recap the device

6

Read the Drugs of Abuse Test results at 5 minutes after adding the sample.

Note: If urine Alcohol strip is integrated in the* DOA/Alcohol Panel Test Device, *the device should be held until the whole alcohol detection pad is wet, which takes about 20 to 30 seconds.
Caution: Results of drug and alcohol after 10 minutes may not be accurate. Results of adulteration strip after 2 minutes may not be accurate.

INTERPRETATION OF RESULTS

Names of drugs on the test could be different depending on the various combination of drugs selected.

APPEARANCE

Drugs of Abuse Panel Test

DRUGS OF ABUSE NEGATIVE

Coloured bands show on both test line zone (T or T1 /T 2) and control line zone (C). This is an indication of negative result for that (those) particular test(s). The negative result does not indicate the absence of drug(s) in the specimen; it only indicates the level of tested drug in the specimen is less than cut-off level.

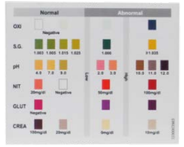
DRUGS OF ABUSE POSITIVE

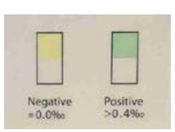
One coloured band form on any strip of the card. One coloured band appears in control line zone. No coloured band is found in test line zone (T or T1 /T 2). This is an indication the level of tested drug(s) in the specimen is above the cut-off level.

DRUGS OF ABUSE INVALID

If there is no coloured band in control line zone (C) of any strip, the test result is invalid. Retest the sample with a new device.

ALCOHOL & ADULTERATION





1. Read Reaction Pads against the Alcohol /Adulteration Test Colour Chart provided.
2. Refer to supplied colour chart for the level of each index to be tested and check if it is in the normal range.

Note: A borderline(+/-) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The DOA/Alcohol Panel Test Device is a qualitative assay. It identifies the drug(s) in human urine at its cut-off concentration or higher. The concentration of the drug(s) cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the DOA/Alcohol Panel Test Device was evaluated in each component strip and in comparison to GC/MS method at the following cut-off concentration: d-amphetamine 1000ng/ml (AMP), secobarbital 300 ng/ml (BAR), oxazepam, 300 ng/ml (BZD), buprenorphine-3-β-d-glucoronide 10ng/ml (BUP), benzoylecgonine 300ng/ml (COC), EDDP 100ng/ml (EDDP), Ketamine 1000ng/ml (KET), methadone 300 ng/ml (MTD), MDMA 500ng/ml (MDMA), (+)methamphetamine 1000 ng/ml (MET), phencyclidine 25 ng/ml (PCP), morphine 300 ng/ml (OPI), morphine 2000 ng/ml (OPI II), oxycodone 100ng/ml (OXY), nor-propoxyphene 300 ng/ml (PPX), 11-nor-Δ^9-THC-9-COOH 50ng/ml (THC), Tramadol 200 ng/ml (TRA) , Nortriptyline 1000 ng/ml (TCA). 6-Acetylmorphine 10 ng/ml (6-MAM), Zolpidem Phenyl-4-carboxylic acid 50 ng/ml (ZOL), Lysergic acid diethylamide 20 ng/ml (LSD), 7-Aminoclonazepam 300 ng/ml (7-ACL), Pregabalin 500 ng/ml (PGB), Mescaline 300 ng/ml (MES), 3,4-Methylenedioxypyrovalerone 500 ng/ml (MDPV), Methcathinone 500 ng/ml (MCAT), Mephedrone 500 ng/ml (MEP), Gabapentin 2000 ng/ml (GAB), Carfentanil 500 ng/ml (CFYL), AB-PINACA 25 ng/ml (K2-AB),, Caffeine 8000 ng/ml (CAF) Ethyl Glucuronide 500/1000 ng/m(ETG), JHW-018 and JWH-073 50 ng/ml(K2) Cotinine 200ng/ml(COT), Fentanyl 10 ng/m(FYL)l and Methaqualone 300 ng/ml(MQL) The results of each component strip are listed below:

1. **Amphetamine** The accuracy of the amphetamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml. Three hundred and forty five (345) urine specimens which composed of one hundred and thirty three (133) d-amphetamine positive samples and two hundred and twelve (212) negative samples were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 98.5, Negative % agreement: 100

2. **Barbiturate** The accuracy of the barbiturate test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of secobarbital. One hundred thirteen (113) urine specimens which composed of sixty four (64) barbiturate positive samples and forty nice (49) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 100, Negative % agreement: 100.

3. **Benzodiazepine** The accuracy of the benzodiazepine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of oxazepam. Three hundred and forty four (344) urine specimens which composed of one hundred and eleven (111) benzodiazepine positive samples and two hundred and thirty three (233) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 98, Negative % agreement: 100

4. **Buprenorphine** The accuracy of the buprenorphine test was evaluated in comparison to GC/MS at a cut-off of 10 ng/ml of buprenorphine-3-β-d-glucoronide. One hundred and one (101) urine specimens which composed of forty nine (49) buprenorphine-3-β-d-glucoronide positive samples and fifty two (52) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 96, Negative % agreement: 100.

5. **Cocaine** The accuracy of the cocaine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of benzoylecgonine. Three hundred and forty four (344) urine specimens which composed of one hundred and twenty one (121) benzoylecgonine positive samples and two hundred and twenty three (223) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 99, Negative % agreement: 99

6. **EDDP** The accuracy of the methadone metabolite (EDDP) test was evaluated in comparison to GC/MS method at a cut-off of 100 ng/mL EDDP. Ninety nine (99) specimens which composed of forty four (44) positive samples and forty five (45) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 98, Negative % agreement: 100

7. **Ketamine** The accuracy of the ketamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml of ketamine. Three hundred and forty four (344) urine specimens which composed of one hundred and twenty seven (127) ketamine positive samples and two hundred and seventeen (217) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 99, Negative % agreement: 100

8. **MDMA** The accuracy of the MDMA test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of (+) methylenedioxymethamphetamine. Eighty (80) urine specimens with GC/MS confirmed MDMA concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 96, Negative % agreement: 95

9. **Methadone** The accuracy of the methadone test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of methadone. Three hundred and forty four (344) urine specimens which composed of one hundred and eighty seven (187) methadone positive samples and one hundred and fifty seven (157) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 100, Negative % agreement: 100.

10. **Methamphetamine** The accuracy of the methamphetamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml of (+) methamphetamine. Three hundred and forty four (344) urine specimens which composed of one hundred and twenty eight (128) methamphetamine positive samples and two hundred and sixteen (216) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 98, Negative % agreement: 100

11. **Opiate** The accuracy of the opiate test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of morphine. Three hundred and forty four (344) urine specimens which composed of one hundred and fifty nine (159) opiate positive samples and one hundred and eighty five (185) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 99, Negative % agreement: 99

12. **Opiate II** The accuracy of the opiate II test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 2000 ng/ml of morphine. One hundred and eight (108) urine specimens which composed of fifty three (53) opiate positive samples and fifty five (55) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 94, Negative % agreement: 100.0.

13. **Oxycodone** The accuracy of the oxycodone test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 100 ng/ml of oxycodone. One hundred and forty four (140) urine specimens which composed of fifty eight (58) opiate positive samples and eighty two (82) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 100, Negative % agreement: 95

14. **Phencyclidine** The accuracy of the PCP test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 25 ng/ml of phencyclidine. Eighty (80) urine specimens which composed of thirty five (35) phencycludine positive samples and forty five (45) negative samples were evaluated in this study. The results are summarised as below:
Positive % agreement: 98, Negative % agreement: 95

15. **Propoxyphene** The accuracy of the propoxyphene test was evaluated in comparison to GC/MS method at a cut-off of 300 ng/ml of nor-propoxyphene. Ninety one (91) propoxyphene positive specimens with GC/MS confirmed nor-Propoxyphene concentration and forty (40) were evaluated in this study. The results are summarised as below:
Positive % agreement: 100, Negative % agreement: 100

16. **THC** The accuracy of the THC test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 50 ng/ml of 11-nor-Δ^9-THC-9-COOH. Three hundred and forty four (344) urine specimens which composed of seventy eight (78) THC positive samples and two hundred sixty six (266) negative samples were evaluated in this study. The results are summarised as below
Positive % agreement: 100, Negative % agreement: 99

17. **Tramadol** The accuracy of the tramadol test was evaluated in comparison to GC/MS at a cut-off of 200 ng/ml of tramadol Eighty one (81) urine specimens with GC/MS confirmed tramadol concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 95, Negative % agreement: 98

18. **TCA** The accuracy of the TCA test was evaluated in comparison to GC/MS at a cut-off of 1000 ng/ml of Nortriptyline. One hundred (100) urine specimens with GC/MS confirmed Nortriptyline concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 98, Negative % agreement: 95

19. 6-MAM The accuracy of the 6-MAM test was evaluated in comparison to GC/MS at a cut-off of 10 ng/ml of 6-Acetylmorphine. One hundred and twenty one (121) urine specimens with GC/MS confirmed 6-Acetylmorphine concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 97, Negative % agreement: 100

20. ZOL The accuracy of the ZOL test was evaluated in comparison to GC/MS at a cut-off of 50 ng/ml of Zolpidem Phenyl-4-carboxylic acid. Ninety six (96) urine specimens with GC/MS confirmed Zolpidem Phenyl-4-carboxylic acid concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 98, Negative % agreement: 99

21. LSD The accuracy of the LSD test was evaluated in comparison to GC/MS at a cut-off of 20 ng/ml of Lysergic acid diethylamide. Ninety five (95) urine specimens with GC/MS confirmed Lysergic acid diethylamide concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 96, Negative % agreement: 98

22. 7-ACL The accuracy of the 7-ACL test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of 7-Aminoclonazepam. One hundred (100) urine specimens with GC/MS confirmed 7-Aminoclonazepam concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 99, Negative % agreement: 100

23. PGB The accuracy of the PGB test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of Pregabalin. One hundred and thirty two (132) urine specimens with GC/MS confirmed Pregabalin concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 96, Negative % agreement: 98

24. MES The accuracy of the MES test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of Mescaline. One hundred and nine (109) urine specimens with GC/MS confirmed Mescaline concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 98, Negative % agreement: 100

25. MDPV The accuracy of the MDPV test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of 3,4-Methylenedioxypyrovalerone. One hundred and six (106) urine specimens with GC/MS confirmed 3,4-Methylenedioxypyrovalerone concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 99, Negative % agreement: 100

26. MCAT The accuracy of the MCAT test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of Methcathinone. Eighty eight (88) urine specimens with GC/MS confirmed Methcathinone concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 100, Negative % agreement: 97

27. MEP The accuracy of the MEP test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of Mephedrone. Two hundred and three (203) urine specimens with GC/MS confirmed Mephedrone concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 97, Negative % agreement: 99

28. GAB The accuracy of the GAB test was evaluated in comparison to GC/MS at a cut-off of 2000 ng/ml of Gabapentin. One hundred and fifty nine (159) urine specimens with GC/MS confirmed Gabapentin concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 97, Negative % agreement: 100

29. CFYL The accuracy of the CFYL test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of Carfentanil. One hundred and seventy eight (178) urine specimens with GC/MS confirmed Carfentanil concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 98, Negative % agreement: 100

30. K2-AB The accuracy of the K2-AB test was evaluated in comparison to GC/MS at a cut-off of 25 ng/ml of AB-PINACA. Two hundred and twenty five (225) urine specimens with GC/MS confirmed AB-PINACA concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 99, Negative % agreement: 98

31. CAF The accuracy of the CAF test was evaluated in comparison to GC/MS at a cut-off of 8000 ng/ml of Caffeine. One hundred and ninety four (194) urine specimens with GC/MS confirmed Caffeine concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 95, Negative % agreement: 100

32. **ETG** The accuracy of the ETG test was evaluated in comparison to GC/MS at a cut-off of 500/1000 ng/ml of Ethyl-β-D-glucuronide. One hundred and eighty (180) urine specimens with GC/MS confirmed Ethyl-β-D-glucuronide concentration were evaluated in this study. The results are summarised and presented below:
ETG500 Positive % agreement: 97, Negative % agreement: 100 ETG1000 Positive % agreement: 97, Negative % agreement: 100

33. **K2** The accuracy of the K2 test was evaluated in comparison to GC/MS at a cut-off of 50 ng/ml of JWH-018-5 pentanoic. One hundred and fifty-five (155) urine specimens with GC/MS confirmed JWH-018-5 pentanoic concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 98, Negative % agreement: 98

34. **COT** The accuracy of the COT test was evaluated in comparison to GC/MS at a cut-off of 200 ng/ml of (-)-Cotinine. One hundred and sixty (160) urine specimens with GC/MS confirmed (-)-Cotinine concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 99, Negative % agreement: 100

35. **FYL** The accuracy of the FYL test was evaluated in comparison to GC/MS at a cut-off of 200 ng/ml of Fentanyl. One hundred and seventy-five (175) urine specimens with GC/MS confirmed Fentanyl concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 99, Negative % agreement: 100

36. **MQL** The accuracy of the MQL test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of Methaqualone. Two hundred and five (205) urine specimens with GC/MS confirmed Methaqualone concentration were evaluated in this study. The results are summarised and presented below:
Positive % agreement: 100, Negative % agreement: 98

B. Sensitivity

The cut-off concentrations (sensitivity level) of the DOA/Alcohol Panel Test Device are determined to be: AMP 1000 ng/ml, BAR, 300 ng/ml, BZO 300 ng/ml, BUP 10 ng/ml, COC 300 ng/ml, EDDP 100 ng/ml, KET 1000 ng/ml, MTD 300 ng/ml, MET 1000 ng/ml, MDMA 500 ng/ml, OPI 300 ng/ml, OPI II 2000 ng/ml, OXY 100 ng/ml, PCP 25 ng/ml , PPX 300 ng/ml, THC 50 ng/ml, 200ng/ml of TRA and TCA 1000 ng/ml. 6-MAM 10 ng/ml, ZOL 50 ng/ml, LSD 20 ng/ml, 7-ACL 300 ng/ml, PGB 500 ng/ml, MDPV 500 ng/ml, MCAT 500 ng/ml, MEP 500 ng/ml, GAB 2000 ng/ml, CFYL 500 ng/ml, K2-AB 25 ng/ml and CAF 8000 ng/ml. ETG 500/1000 ng/ml, K2 50 ng/ml, COT 200 ng/ml, FYL 10 ng/ml and MQL 300 ng/ml.

C. Precision
The precision of the DOA/Alcohol Panel Test Device was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 40 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.

D. Specificity
The specificity for the DOA/Alcohol Panel Test Device was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing
The performance of the DOA/Alcohol Panel Test Device at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.5 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed did not interfere with the DOA/Alcohol Panel Test Device at the concentrations listed below.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

2. Specificity
The following table lists compounds that are detected by the DOA/Alcohol Panel Test Device which produced positive results when tested at levels equal or greater than the concentrations listed below:

The following compounds show no cross-reactivity at concentrations up to100 ug/mL unless specified in the table above.

Tests	Compounds	Cut-off (ng/ml)
Amphetamine	D-Amphetamine	1,000
	l-Amphetamine	>100,000
	d-methamphetamine	>100,000
	l-methamphetamine	>100,000
	3,4-Methylenedioxyamphetamine	1,250
	3,4-Methylenedioxy-methamphetamine	>100,000
	3,4-Methylenedioxyethylamphetamine	>100,000
	Paramethoxyamphetamine	625
	Phentermine	1250
	Tyramine	>100,000
Barbiturate	Secobarbital	300
	Allobarbital	1250
	Alphenal	625
	Amobarbital	625
	Aprobarbital	188
	Butabarbital	94
	Butalbital	2500
	Butethal	200
	Cyclopentobarbital	400
	Pentobarbital	1,000
	Phenobarbital	300
Buprenorphine	Buprenorphine	5
	Buprenorphine–3–β–D–Glucuronide	5
	Norbuprenorphine	25
	Norbuprenorphine–3–β–D–Glucuronide	50
Benzoxiazepines	Oxazepam	300
	Alprazolam	125
	Bromazepam	625
	Chlordiazepoxide	2500
	Clobazam	63
	Clonazepam	2500
	Clorazepate	3330
	Desalkflurazepam	250
	Diazepam	250
	Estazolam	5000
	Fentanyl	>100,000
	Flunitrazepam	375
	Flurazepam	>100,000
	Lorazepam	1250
	Lormetazepam	1250
	Medazepam	>100,000
	Midazolam	>100,000
	Nitrazepam	25000
	Norchlordiazepoxide	250
	Nordiazepam	500
	Prazepam	>100,000
	Temazepam	63
	Triazolam	5000
Cocaine	Benzoylecgonine	300
	Cocaine	1,000
	Ecgonine	100,000
	Ecgonine Methyl Ester	>100,000
EDDP	EDDP	100
	Meperidine	>100,000
	Methadone	>100,000

	Norfentanyl	>100,000
	Phencyclidine	>100,000
	Promazine	50000
	Promethazine	25000
	Prothipendyl	50,000
	Prozine	12500
Ketamine	Ketamine	1,000
	Norketamine	1,000
	Dextromethorphan	500
MDMA	3,4-Methylenedioxy-methamphetamine	500
	d-Amphetamine	>100,000
	l-Amphetamine	>100,000
	d-methamphetamine	>100,000
	l-methamphetamine	>100,000
	3,4-Methylenedioxyamphetamine	2,500
	3,4-Methylenedioxyethylamphetamine	156
	Paramethoxyamphetamine	50,000
	Paramethoxymethamphetamine	>100,000
Methamphetamine	d-Methamphetamine	1,000
	Chloroquine	25,000
	Fenfluramine	12,500
	l-Methamphetamine	1,000
	Mephentermine hemisulfate salt	31250
	3,4-Methylenedioxyethylamphetamine	50000
	3,4-Methylenedioxy-methamphetamine	313
	Paramethoxymethamphetamine	625
	(-)-Ephedrine	4000
Methadone	Methadone	300
	(-)-alpha-methadol	2,000
Opiate	Morphine	300
	Acetylcodeine	150
	Buprenorphine	>10000
	Codeine	250
	Diacetyl Morphin	250
	Dihydrocodeine	586
	Ethylmorphine	200
	Hydrocodone	12500
	Hydromorphone	12500
	6-Monoacetylmorphine	250
	Morphine-3-glucuronid	2500
	Nalorphine	25000
	Thebaine	25000
Opiate II	Morphine	1000
	Acetylcodeine	1000
	Buprenorphine	>10000
	Codeine	1000
	Diacetylmorphine (Heroin)	3000
	Dihydrocodeine	1000
	Ethylmorphine	200
	Hydromorphone	25000
	Hydrocodone	50000
	Merperidine	>100,000
	6-Monoacetylmorphine (6-MAM)	3000
	Morphine-3-β-d-glucuronide	10000
	Nalorphine Hydrochloride	>100,000
	Oxycodone	>100,000
	Oxymorphone	>100,000
	Rifampicine	>100,000
	Thebaine	50000
OXY100	Oxycodone	100
	Hydrocodone	6250
	Hydromorphone	50000
	Naloxone	50000
	Oxymorphone	250
PCP	Phencyclidine	25
	Hydrocodone	>100,000
	Hydromorphone	>100,000
	4-hydroxyphencyclidine	75
Propoxyphene	D-Propoxyphene	300
	D-Norpropoxyphene	5000
TCA	Nortriptyline HCl	1000
	Amitriptyline	150
	Clomipramine	>100000
	Cyclobenzaprine	12500
	Desipramine	188
	Doxepin	2000

	Imipramine	2500
	Maprotiline	750
	Nortriptyline	3125
	Nordoxepin	500
	Opipramol	1563
	Promazine	1000
	Promethazine	6250
	Prothipendyl	25000
	Protryptyline	6250
	Prozine	1250
	Trimipramine	>100,000
THC	11-nor-Δ9-THC-9-COOH	25
	11-nor-Δ8-THC-9-COOH	15
	Δ 8-Tetrahydrocannabinol	7500
	Δ 9-Tetrahydrocannabinol	7500
	Cannabinol	10000
Tramadol	Cis-Tramadol	200
	N-Desmethyl-cis tramadol	500
	O-Desmethyl-cis tramadol	20,000
	Netrexone	10,000
	Tetrahydrozoline	10,000
	Dihydrocodeine	50,000
6-MAM	6-Monoacetylmorphine	10
	Acetylcodeine	>10,000
	Buprenorphine	>10,000
	Codeine	>10,000
	Diacetylmorphine	1000
	Dihydrocodeine	>10,000
	Ethylmorphine	>10,000
	Hydrocodone	>10,000
	Hydromorphone	5000
	Morphine	10000
	Morphine-3-glucuronide	>10,000
	Nalorphine	5000
	Thebaine	>20,000
ZOL	Zolpidem Phenyl-4-carboxylic	50
	Zolpidem	>10,000
LSD	Lysergic acid diethylamide	20
7-ACL	7-amine-clonazepam	300
	Oxazepam	>10,000
	Alprazolam	>10,000
	Bromazepam	>10,000
	Chlordiazepoxide	>10,000
	Clobazam	>10,000
	Clonazepam	10,000
	Clorazepate dipotassium	>10,000
	Desalkylflurazepam	>10,000
	Diazepam	>10,000
	Estazolam	>10,000
	Flunitrazepam	>50,000
	(±) Lorazepam	10,000
	Midazolam	>100,000
	Nitrazepam	>10,000
	Norchlordiazepoxide	>100,000
	Nordiazepam	>100,000
	Temazepam	>10,000
PGB	Pregabalin	500
MES	Mescaline	300
MDPV	MDPV	500
MCAT	Methcathinone	500
	4-MMC（Mephedrone）	520
	3-MMC (3-methylmethcathinone)	500
	4-MEC (4-methylethcathinone)	550
	Cathinone	>100,000
	MDPV	>10,000
MEP	Mephedrone	500
	Methcathinone	500
GAB	Gabapentin	2000
	Pregbalin	>100000
CFYL	CarFentanyl	500
	Fentanyl	100
K2-AB	AB- PINACA	25
	AB-Fubinaca	40
	UR-144 5-Pentanoic acid metabolite	5,000
	UR-144	>10,000
	AKB48	>10,000
CAF	Caffeine	8,000

	Theophylline	100,000
ETG	Ethyl Glucuronide	500
	Ethanol	>100,000
	D-Glucuronic Acid	>100,000
	Morphine-3-b-D-glucuronide	>100,000
ETG II*	Ethyl Glucuronide	1000
FYL	Fentanyl and Fentanyl metabolites	10
	Fentanyl	100
	Norfentanyl	>10,000
COT	(-)-Cotinine	200
	(-)-Nicotine	6250
MQL	Methaqualone	300
	Amitriptyline	50,000
	Carbamazepine	20,000
	Nortriptyline	50,000
	Phenytoin	40,000
	Theophylline	40,000

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MATRIX EC REP

Matrix Diagnostics Limited
Unit 9 Meridian Business Park
Fleming Road, Waltham Abbey
EN9 3BZ, United Kingdom
Tel : +44 (0) 1992 762 678
Fax: +44 (0) 1992 761 798
Email: info@matrixdiagnostics.co.uk
www.matrixdiagnostics.co.uk

Emergo Europe
Molenstraat 152513 BH The Hague
The Netherlands

Tel: +31(0)70.345.8570
Fax: +31(0)70.346.7299

MATRIXDIAGNOSTICS

Number:1110026071