CLEARTEST® DIAGNOSTIK

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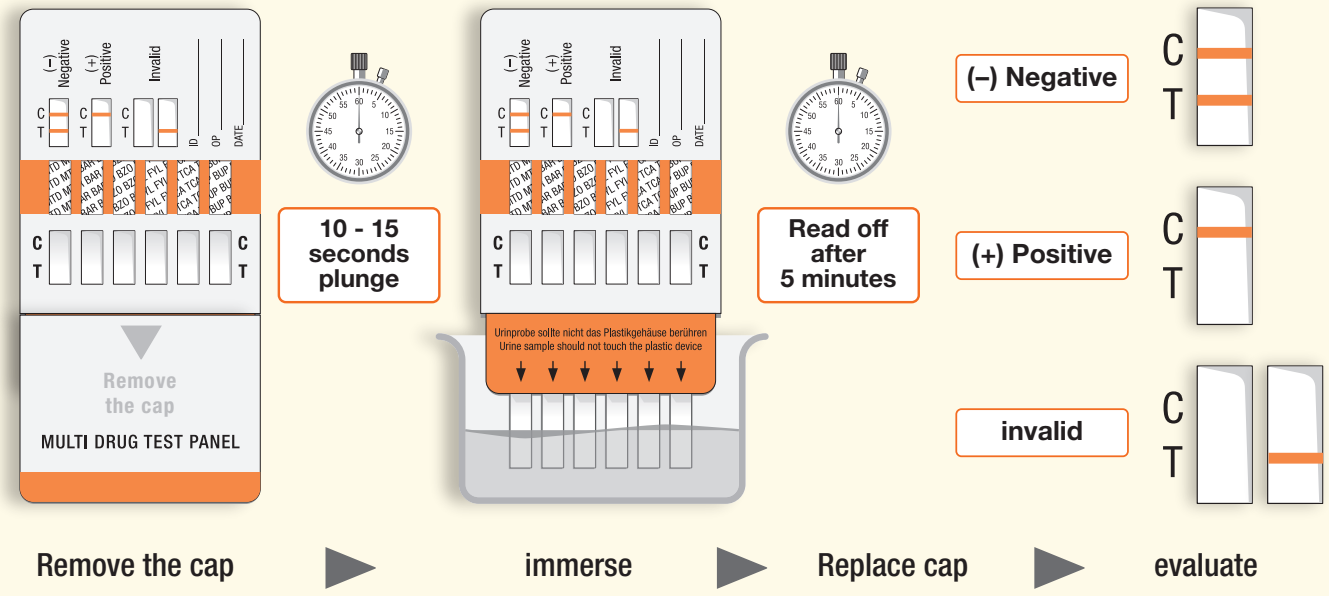
MULTI-DIP-6/12

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

Only for professional In-vitro-Diagnostic

IVD

Instruction Sheet for testing of any combination of the following drugs: AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/MQL/OPI/PCP/PPX/TCA/TML/KET/OXY/COT/EDDP/FYL/K2/6-MAM/MDA/ETG/CLO



A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for In-vitro-diagnostic use only.

INTENDED USE

The Multi-Dip-6/12 Rapid Test Panel is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-Off (ng/mL)
Amphetamine (AMP1,000)	d-Amphetamine	1,000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR 300)	Secobarbital	300
Barbiturates (BAR 200)	Secobarbital	200
Benzodiazepines (BZO 500)	Oxazepam	500
Benzodiazepines (BZO 300)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO 100)	Oxazepam	100
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC 300)	Benzoylecgonine	300
Cocaine (COC 100)	Benzoylecgonine	100
Marijuana (THC150)	11-nor-Δ9-THC-9 COOH	150
Marijuana (THC 50)	11-nor-Δ9-THC-9 COOH	50
Marijuana (THC 25)	11-nor-Δ9-THC-9 COOH	25
Methadone (MTD 300)	Methadone	300
Methadone (MTD 200)	Methadone	200
Methamphetamine (MET 1,000)	d-Methamphetamine	1,000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET 300)	d-Methamphetamine	300
Methylenedioxymethamphetamine (MDMA 500)	d,l-Methylenedioxymethamphetamine	500
Methylenedioxymethamphetamine (MDMA 1,000)	d,l-Methylenedioxymethamphetamine	1,000
Morphine (MOP 300)	Morphine	300
Morphine (MOP 100)	Morphine	100
Methaqualone(MQL)	Methaqualone	300
Opiate (OPI 2,000)	Morphine	2,000
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Tramadol (TML)	Cis-Tramadol	100
Ketamine (KET 1,000)	Ketamine	1,000
Ketamine (KET 500)	Ketamine	500
Ketamine (KET 300)	Ketamine	300
Ketamine (KET 100)	Ketamine	100
Oxycodone (OXY)	Oxycodone	100
Cotinine(COT200)	Cotinine	200
Cotinine(COT100)	Cotinine	100
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Fentanyl(FYL20)	Norfentanyl	20
Fentanyl(FYL10)	Norfentanyl	10
Synthetic Marijuana (K2-50)	JWH-018, JWH-073	50

Test	Calibrator	Cut-Off (ng/mL)
Synthetic Marijuana (K2-30)	JWH-018, JWH-073	30
6-mono-aceto-morphine (6-MAM10)	6-MAM	10
(±) 3,4-Methylenedioxy-Amphetamine (MDA500)	(±) 3,4-Methylenedioxy-Amphetamine	500

Configurations of the Multi-Dip-6/12 Rapid Test Panel come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The Multi-Dip-6/12 Rapid Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP 1,000)

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 (CNS) 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 Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of amphetamines 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).[1]

BARBITURATES (BAR 300)

Barbiturates are CNS 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[2]

The Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/ml. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.

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 benzodiazepines in urine is 3–7 days.

The Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/ml. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations. The plasma half life of Buprenorphine is 2–4 hours.7While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days. Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes. The Multi-Dip-6/12 Rapid Test Panel yields a positive result when the Buprenorphine in urine exceeds 10 ng/ml.

COCAINE (COC 300)

Cocaine is a potent central nervous system 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 benzoylecgonine.[3,4] Benzoylecgonine, 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.[4] TheMulti-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of benzoylecgonine 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).1

MARIJUANA (THC 50)

THC (Δ9-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-Δ9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of THC-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).[1]

METHADONE (MTD 300)

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 beprescribed 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.[7] The Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of methadone in urine exceeds 300 ng/ml. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

METHAMPHETAMINE (MET 1,000)

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 have a half-life of 9–24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10–20 % of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3–5 days, depending on urine pH level. The Multi-Dip-6/12 Rapid Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The Multi-Dip-6/12 Rapid Test Panel yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.5 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 Oberlender, 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 Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/ml. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxymethamphetamine positive specimens.

MORPHINE (MOP 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. 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.2 The Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

TRICYCLIC ANTIDEPRESSANTS (TCA 1,000)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS 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 Multi-Dip-6/12 Rapid Test Panel yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/ml. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

FENTANYL (FYL 20)

Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations “Single Convention of narcotic drug in 1961”. Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain[1]. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc[2,3], which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose[4]. The FYL Rapid Test Dipstick (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of FYL in urine. The FYL Rapid Test Dipstick (Urine) yields a positive result when FYL in urine exceeds 20 ng/ml.

PRINCIPLE

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

REAGENTS

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for In-vitro-diagnostic use only. The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test panel should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2–30 °C. The test is stable through the expiration date printed on the sealed pouch. The test Panels 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 in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

SPECIMEN STORAGE

Urine specimens may be stored at 2–8 °C 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 Panels
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to reach room temperature (15–30 °C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test panel.
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. The result should be read at 5 minutes. Results may be stable up to 1 hour after test initiation.

INTERPRETATION OF RESULTS

NEGATIVE:* A colored line appears in the Control region (C) and colored lines appears in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A 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. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Multi-Dip-6/12 Rapid Test Panel 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.[1,10]
2. There is a possibility that technical or procedural errors, as well as 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.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
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. This 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.

EXPECTED VALUES

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

Positive result means the concentration of drug is above the detectable level.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Multi-Drug Rapid Test Cup and commercially available drug rapid tests. Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS.

Method		GC/MS		% agreement with GC/MS
Multi-Drug Rapid Test Cup		Positive	Negative	
AMP 1,000	Positive	103	3	98.1 %
	Negative	2	142	97.9 %
AMP 500	Positive	110	2	99.1 %
	Negative	1	137	98.6 %
AMP 300	Positive	116	2	99.1 %
	Negative	1	131	98.5 %
BAR 300	Positive	98	2	96.1 %

Method		GC/MS		% agreement with GC/MS
Multi-Drug Rapid Test Cup		Positive	Negative	
AMP 1	Positive	103	3	98.1 %
	Negative	2	142	97.9 %
AMP 500	Positive	110	2	99.1 %
	Negative	1	137	98.6 %
AMP 300	Positive	116	2	99.1 %
	Negative	1	131	98.5 %
BAR 300	Positive	98	2	96.1 %
	Negative	4	146	98.6 %

BAR 200	Positive	101	3	95.3%
	Negative	5	141	97.9%
BZO 500	Positive	112	3	98.2%
	Negative	2	133	97.8%
BZO 300	Positive	121	1	98.4%
	Negative	2	126	99.2%
BZO 200	Positive	127	2	99.2%
	Negative	1	120	98.4%
BZO 100	Positive	128	3	99.2%
	Negative	1	118	97.5%
BUP	Positive	105	0	99.1%
	Negative	1	144	>99.9%
COC 300	Positive	111	3	98.2%
	Negative	2	134	97.8%
COC 100	Positive	117	4	99.2%
	Negative	1	128	97.0%
THC 150	Positive	86	4	94.5%
	Negative	5	155	97.5%
THC 50	Positive	92	3	97.9%
	Negative	2	153	98.1%
THC 25	Positive	95	4	96.9%
	Negative	3	148	97.4%
MTD 300	Positive	89	2	98.9%
	Negative	1	158	98.8%
MTD 200	Positive	91	2	98.7%
	Negative	1	156	98.7%
MET 1	Positive	76	5	96.2%
	Negative	3	166	97.1%
MET 500	Positive	83	5	97.6%
	Negative	2	160	97.0%
MET 300	Positive	88	4	97.8%
	Negative	2	156	97.5%
MDMA 1	Positive	99	1	98.0%
	Negative	2	148	99.3%
MDMA 500	Positive	102	1	98.1%
	Negative	2	145	99.3%
MOP 300	Positive	95	7	95.0%
	Negative	5	143	95.3%
MOP 100	Positive	98	5	97.0%
	Negative	3	144	96.6%
MQL	Positive	79	11	89.8%
	Negative	9	151	93.2%

OPI	Positive	117	8	96.7%
	Negative	4	121	93.8%
PCP	Positive	85	5	92.4%
	Negative	7	153	96.8%
PPX	Positive	97	9	96.0%
	Negative	4	140	94.0%
TCA	Positive	91	13	94.8%
	Negative	5	141	91.6%
TML	Positive	82	12	88.2%
	Negative	11	145	92.4%
KET 1	Positive	77	3	97.5%
	Negative	2	168	98.2%
KET 500	Positive	81	3	97.6%
	Negative	2	164	98.2%
KET 300	Positive	89	4	96.7%
	Negative	3	154	97.5%
KET 100	Positive	97	4	96.0%
	Negative	4	145	97.3%
OXY 100	Positive	84	1	97.7%
	Negative	2	163	99.4%
COT 200	Positive	88	4	96.7%
	Negative	3	155	97.5%
COT 100	Positive	93	3	97.9%
	Negative	2	152	98.1%
EDDP 300	Positive	92	1	97.9%
	Negative	2	155	99.4%
EDDP 100	Positive	95	5	96.9%
	Negative	3	147	96.7%
FYL 20	Positive	79	1	98.8%
	Negative	1	169	99.4%
FYL 10	Positive	80	1	98.8%
	Negative	1	168	99.4%
K2-50	Positive	78	3	97.5%
	Negative	2	167	98.2%
K2-30	Positive	82	2	97.6%
	Negative	2	164	98.8%
6-MAM 10	Positive	93	2	98.9%
	Negative	1	154	98.7%
MDA 500	Positive	103	3	98.1%
	Negative	2	142	97.9%

% Agreement with Commercial Kit											
	AMP	AMP	AMP	BAR	BAR	BZO	BZO	BZO	BZO	BUP	COC
	1	500	300	300	200	500	300	200	100		300
Positive Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Negative Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Total Results	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%

% Agreement with Commercial Kit											
	COC	THC	THC	THC	MTD	MTD	MET	MET	MET	MDMA	MDMA
	100	150	50	25	300	200	1	500	300	1	500
Positive Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Negative Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Total Results	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%

% Agreement with Commercial Kit											
	MOP	MOP	MQL	OPI	PCP	PPX	TCA	TML	KET	KET	KET
	300	100							1	500	300
Positive Agreement	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	*	*	>99.9%	>99.9%	>99.9%
Negative Agreement	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	*	*	>99.9%	>99.9%	>99.9%
Total Results	>99.9%	>99.9%	>99.9%	*	>99.9%	>99.9%	*	*	>99.9%	>99.9%	>99.9%

% Agreement with Commercial Kit											
	KET	OXY	COT	COT	EDDP	EDDP	FYL	FYL	K2	K2	6-MAM
	100		200	100	300	100	20	10	50	30	10
Positive Agreement	>99.9%	*	*	*	*	*	*	*	*	*	*
Negative Agreement	>99.9%	*	*	*	*	*	*	*	*	*	*
Total Results	>99.9%	*	*	*	*	*	*	*	*	*	*

* Note: Based on GC/MS data instead of Commercial Kit.

PRECISION

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ±50 % and ±25 % cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP 1,000)							
Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	6	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,25	10	1	9	2	8	2	8
1,5	10	0	10	0	10	0	10

AMPHETAMINE (AMP 500)							
Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	2	8	1	9	2	8
750	10	0	10	0	10	0	10

AMPHETAMINE (AMP 300)							
Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	8	2	8	2
375	10	2	8	2	8	2	8
450	10	0	10	0	10	0	10

BARBITURATES (BAR 300)							
Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	8	2	9	1
375	10	2	8	1	9	2	8
450	10	0	10	0	10	0	10

BARBITURATES (BAR 200)							
Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	1	9
300	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 500)							
Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	8	2
625	10	1	9	2	8	1	9
750	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 300)							
Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 200)							
Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	8	2	9	1
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 100)							
Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	8	2	7	3
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

Buprenorphine (BUP)							
Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
07. Mai	10	9	1	9	1	8	2
12. Mai	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

COCAINE (COC 300)							
Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

COCAINE (COC 100)							
Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	2	8	2	8	2	8
150	10	0	10	0	10	0	10

MARIJUANA (THC150)							
11-nor-D9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112.5	10	9	1	9	1	9	1
187.5	10	2	8	1	9	1	9
225	10	0	10	0	10	0	10

MARIJUANA (THC50)							
11-nor-D9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	1	9	1	9	2	8
75	10	0	10	0	10	0	10

MARIJUANA (THC25)							
11-nor-D9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12. Mai	10	10	0	10	0	10	0
18.75	10	8	2	8	2	8	2
31.25	10	1	9	1	9	2	8
37.5	10	0	10	0	10	0	10

METHADONE (MTD300)							
Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

METHADONE (MTD200)							
Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	8	2	8	2	8	2
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

METHAMPHETAMINE (MET1,000)							
Methampheta-mine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1,25	10	1	9	2	8	1	9
1,5	10	0	10	0	10	0	10

METHAMPHETAMINE (MET 500)							
Methampheta-mine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

METHAMPHETAMINE (MET300)							
Methampheta-mine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA1, 000) Ecstasy							
Methylenedioxy-methampheta-mine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	8	2
1,25	10	1	9	1	9	1	9
1,5	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500) Ecstasy							
Methylenedioxy-methampheta-mine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

MORPHINE (MOP 300)							
Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MORPHINE (MOP 100)							
Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

METHAQUALONE (MQL 300)							
Methaqualone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MORPHINE/OPIATE (OPI 2,000)							
Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
1	10	10	0	10	0	10	0
1,5	10	9	1	9	1	9	1
2,5	10	1	9	1	9	1	9
3	10	0	10	0	10	0	10

PHENCYCLIDINE (PCP)							
Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12. Mai	10	10	0	10	0	10	0
18.75	10	8	2	9	1	9	1
31.25	10	1	9	1	9	1	9
37.5	10	0	10	0	10	0	10

PROPOXYPHENE (PPX)							
Propoxyphene conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

TRICYCLIC ANTIDEPRESSANTS (TCA)							
Nortriptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	8	2
1,25	10	1	9	1	9	1	9
1,5	10	0	10	0	10	0	10

Tramadol (TML)							
Tramadol conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	8	2
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

KETAMINE (KET1, 000)							
Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,25	10	1	9	1	9	2	8
1,5	10	0	10	0	10	0	10

KETAMINE (KET500)							
Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	8	2
625	10	1	9	1	9	2	8
750	10	0	10	0	10	0	10

KETAMINE (KET300)							
Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

KETAMINE (KET100)							
Ketamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	2	8
150	10	0	10	0	10	0	10

Oxycodone (OXY100)							
Oxycodone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

Cotinine (COT 200)							
Cotinine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
100	10	10	0	10	0	10	0
150	10	9	1	9	1	9	1
250	10	1	9	1	9	2	8
300	10	0	10	0	10	0	10

COTININE (COT 100)							
Cotinine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 300)							
EDDP conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	2	8	1	9
450	10	0	10	0	10	0	10

2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 100)							
EDDP conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
75	10	9	1	9	1	9	1
125	10	1	9	1	9	1	9
150	10	0	10	0	10	0	10

Fentanyl (FYL20)							
FYL conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

Fentanyl (FYL10)							
FYL conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
07. Mai	10	9	1	9	1	9	1
12. Mai	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

K2 50							
K2 conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	8	2	8	2	9	1
62.5	10	1	9	2	8	2	8
75	10	0	10	0	10	0	10

K2 30							
K2 conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
15	10	10	0	10	0	10	0
22. Mai	10	8	2	9	1	9	1
37.5	10	1	9	1	9	1	9
45	10	0	10	0	10	0	10

6-MAM							
6-MAM conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
07. Mai	10	9	1	9	1	9	1
12. Mai	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

MDA 500							
MDA conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

ANALYTICAL SENSITIVITY

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

Drug Concentration Cut-off Range	AMP 1,000		AMP 500		AMP 300		BAR 300		BAR 200		BZO 500		BZO 300		BZO 200	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25 % Cut-off	26	4	25	5	27	3	27	3	26	4	27	3	27	3	27	3
Cut-off	15	15	15	15	15	15	16	14	15	15	15	15	15	15	16	14
+25 % Cut-off	3	27	3	27	4	26	4	26	3	27	4	26	3	27	3	27
+50 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	BZO100		BUP		COC 300		COC 100		THC 150		THC 50		THC 25		MTD 300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25 % Cut-off	27	3	26	4	26	4	27	3	27	3	26	4	27	3	27	3
Cut-off	14	16	14	16	13	17	16	14	15	15	14	16	16	14	15	15
+25 % Cut-off	3	27	3	27	3	27	4	26	4	26	3	27	4	26	3	27
+50 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	MTD200		MET 1,000		MET 500		MET 300		MDMA 1,000		MDMA 500		MOP 300		MOP 100	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25 % Cut-off	27	3	26	4	25	5	27	3	26	4	25	5	26	4	27	3
Cut-off	15	15	14	16	15	15	16	14	15	15	14	16	15	15	16	14
+25 % Cut-off	4	26	3	27	4	26	3	27	5	25	4	26	3	27	4	26
+50 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	OPI		PCP		PPX		TCA		TML		KET 1,000		KET 500		KET 300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25 % Cut-off	27	3	26	4	27	3	25	5	27	3	26	4	27	3	26	4
Cut-off	15	15	15	15	14	16	15	15	15	15	16	14	15	15	15	15
+25 % Cut-off	5	25	3	27	4	26	3	27	4	26	4	26	3	27	3	27
+50 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	KET100		MQL		OXY		COT200		COT100		EDDP 300		EDDP 100		FYL20	
Cut-off Bereich	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50 % Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25 % Cut-off	27	3	27	3	27	3	27	3	27	3	27	3	27	3	27	3
Cut-off	15	15	15	15	15	15	15	15	14	16	14	16	15	15	15	15
+25 % Cut-off	3	27	4	26	4	26	4	26	4	26	4	26	3	27	3	27
+50 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300 % Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	FYL10		K2 50		K2 30		6-MAM 10		MDA 500	
Cut-off Bereich	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	30	0	30	0	30	0	30	0	30	0
-50 % Cut-off	30	0	30	0	30	0	30	0	30	0
-25 % Cut-off	27	3	26	4	27	3	27	3	26	4
Cut-off	15	15	15	15	16	14	15	15	15	15
+25 % Cut-off	4	26	3	27	4	26	4	26	3	27
+50 % Cut-off	0	30	0	30	0	30	0	30	0	30
+300 % Cut-off	0	30	0	30	0	30	0	30	0	30

ANALYTICAL SPECIFICITY

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-Drug Rapid Test Cup at 5 minutes.

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Phentermine	1
L-Amphetamine	25	Maprotiline	50
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	6
		D-Amphetamine	1
AMPHETAMINE (AMP 500)			
D,L-Amphetamine sulfate	150	Phentermine	500
L-Amphetamine	12,5	Maprotiline	25
(±) 3,4-Methylenedioxy amphetamine	250	Methoxyphenamine	3
		D-Amphetamine	500
AMPHETAMINE (AMP 300)			
D,L-Amphetamine sulfate	75	Phentermine	300
L-Amphetamine	10	Maprotiline	15
(±) 3,4-Methylenedioxy amphetamine	150	Methoxyphenamine	2
		D-Amphetamine	300
BARBITURATES (BAR 300)			
Amobarbital	5	Alphenol	600
5,5-Diphenylhydantoin	8	Aprobarbital	500
Allobarbital	600	Butabarbital	200
Barbital	8	Butalbital	8
Talbutal	200	Butethal	500
Cyclopentobarbital	30	Phenobarbital	300
Pentobarbital	8	Secobarbital	300
BARBITURATES (BAR 200)			
Amobarbital	3	Alphenol	400
5,5-Diphenylhydantoin	5	Aprobarbital	300
Allobarbital	400	Butabarbital	150
Barbital	5	Butalbital	5
Talbutal	150	Butethal	300
Cyclopentobarbital	20	Phenobarbital	200
Pentobarbital	5	Secobarbital	200
BENZODIAZEPINES (BZO 500)			
Alprazolam	200	Bromazepam	1,5
a-hydroxyalprazolam	2,5	Chlordiazepoxide	1,5
Clobazam	300	Nitrazepam	300
Clonazepam	800	Norchlordiazepoxide	200
Clorazepate dipotassium	800	Nordiazepam	1,5
Delorazepam	1,5	Oxazepam	500
Desalkylflurazepam	300	Temazepam	300
Flunitrazepam	300	Diazepam	500
(±) Lorazepam	5	Estazolam	10
RS-Lorazepam glucuronide	300	Triazolam	5
Midazolam	10		
BENZODIAZEPINES (BZO 300)			
Alprazolam	100	Bromazepam	900
a-hydroxyalprazolam	1,5	Chlordiazepoxide	900
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepate dipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Flunitrazepam	200	Diazepam	300
(±) Lorazepam	3	Estazolam	6
RS-Lorazepam glucuronide	200	Triazolam	3
Midazolam	6		
BENZODIAZEPINES (BZO 200)			
Alprazolam	70	Bromazepam	600
a-hydroxyalprazolam	1	Chlordiazepoxide	600
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepate dipotassium	300	Nordiazepam	600
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120	Temazepam	70
Flunitrazepam	120	Diazepam	200
(±) Lorazepam	2	Estazolam	4
RS-Lorazepam glucuronide	120	Triazolam	2
Midazolam	4		
BENZODIAZEPINES (BZO 100)			
Alprazolam	40	Bromazepam	300
a-hydroxyalprazolam	500	Chlordiazepoxide	300
Clobazam	60	Nitrazepam	60
Clonazepam	150	Norchlordiazepoxide	40
Clorazepate dipotassium	150	Nordiazepam	300
Delorazepam	300	Oxazepam	100
Desalkylflurazepam	60	Temazepam	40
Flunitrazepam	60	Diazepam	100
(±) Lorazepam	1	Estazolam	2
RS-Lorazepam glucuronide	60	Triazolam	1
Midazolam	2		
BUPRENORPHINE (BUP)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20
Cocaine HCl	200	Ecgonine	30
COCAINE (COC 100)			
Benzoylecgonine	100	Cocaethylene	7
Cocaine HCl	80	Ecgonine	10
MARIJUANA (THC150)			
Cannabinol	100	g8-THC	50
11-nor-Δ8-THC-9 COOH	100	g9-THC	50
11-nor-9-ΔTHC-9 COOH	150		
MARIJUANA (THC50)			
Cannabinol	35	g8-THC	17
11-nor-Δ8-THC-9 COOH	30	g9-THC	17
11-nor-Δ9-THC-9 COOH	50		
MARIJUANA (THC25)			
Cannabinol	17,5	g8-THC	8,5
11-nor-Δ8-THC-9 COOH	15	g9-THC	8,5
11-nor-Δ9-THC-9 COOH	25		
METHADONE (MTD300)			
Methadone	300	Doxylamine	100
METHADONE (MTD200)			
Methadone	200	Doxylamine	65
METHAMPHETAMINE (MET1, 000)			
renimatehpmahtemyxordyH-	25	(±)-3,4-Methylenedioxy-	12,5
D-Methamphetamine	1	methamphetamine	
L-Methamphetamine	20	Mephentermine	50
METHAMPHETAMINE (MET500)			
renimatehpmahtemyxordyH-	12,5	(±)-3,4-Methylenedioxy-	6,25
D-Methamphetamine	500	methamphetamine	
L-Methamphetamine	10	Mephentermine	25
METHAMPHETAMINE (MET300)			
renimatehpmahtemyxordyH-	7,5	(±)-3,4-Methylenedioxy-	3,75
D-Methamphetamine	300	methamphetamine	
L-Methamphetamine	6	Mephentermine	15
METHYLENEDIOXYMETHAMPHETAMINE (MDMA1, 000) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	1	3,4-Methylenedioxyethyl-amphetamine	600
(±)3,4-Methylenedioxyampheta-mine HCl	6		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA500) Ecstasy			

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
(±)3,4-Methylenedi-oxymetha-mphetamine HCl	500	3,4-Methylenedi-oxyethyl-amphe-tamine	300
(±) 3,4-Methylenedi-oxyamphetamine HCl	3		
MORPHINE (MOP 300)			
Codeine	200	Norcodeine	6
Levorphanol	1,5	Normorphone	50
Morphine-3-β-D-Glucuronide	800	Oxycodone	30
Ethylmorphine	6	Oxymorphone	50
Hydrocodone	50	Procaine	15
Hydromorphone	3	Thebaine	6
6-Monoacethylmor-phine	300	Morphine	300
MORPHINE (MOP 100)			
Codeine	80	Norcodeine	2
Levorphanol	500	Normorphone	20
Morphine-3-□-D-Glucuronide	300	Oxycodone	10
Ethylmorphine	2	Oxymorphone	20
Hydrocodone	20	Procaine	5
Hydromorphone	1	Thebaine	2
6-Monoacethylmor-phine	200	Morphine	100
Methaqualone (MQL 300)			
Methaqualone	300		
MORPHINE/OPIATE (OPI 2,000)			
Codeine	2	Morphine	2
Ethylmorphine	3	Norcodeine	25
Hydrocodone	50	Normorphone	50
Hydromorphone	15	Oxycodone	25
Levorphanol	25	Oxymorphone	25
6-Monoacetylmorphine	3	Procaine	50
Morphine 3-b-D-glucuronide	2	Thebaine	25
PHENCYCLIDINE (PCP)			
Phencyclidine	25	4-Hydroxyphen-cyclidine	12,5
PROPOXYPHENE (PPX)			
D-Propoxyphene	300	D-Norpropoxy-phene	300
TRICYCLIC ANTIDEPRESSANTS (TCA)			
Nortriptyline	1	Imipramine	400
Nordoxepine	500	Clomipramine	50
Trimipramine	3	Doxepine	2
Amitriptyline	1,5	Maprotiline	2
Promazine	3	Promethazine	50
Desipramine	200	Perphenazine	50
Cyclobenzaprine	2		
Tramadol (TML)			
n-Desmethyl-cis-tramadol	200	o-Desmethyl-cis-tramadol	10
Cis-tramadol	100	Phencyclidine	100
Procyclidine	100	d,l-O-Desmethyl venlafaxine	50
KETAMINE (KET1, 000)			
Ketamine	1	Benzphetamine	25
Dextromethorphan	2	(+) Chlorpheni-ramine	25
Methoxyphenamine	25	Clonidine	100
d-Norpropoxyphene	25	EDDP	50
Promazine	25	4-Hydroxyphen-cyclidine	50
Promethazine	25	Levorphanol	50
Pentazocine	25	MDE	50
Phencyclidine	25	Meperidine	25
Tetrahydrozoline	500	d-Methamphet-amine	50
Mephentermine	25	l-Methamphet-amine	50
(1R, 2S) - (-)-Ephedrine	100	3,4-Methylendi-oxymethampheta-mine (MDMA)	100
Disopyramide	25	Thioridazine	50
KETAMINE (KET500)			
Ketamine	500	Benzphetamine	12,5
Dextromethorphan	1	(+) Chlorpheni-ramine	12,5

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
Methoxyphenamine	12,5	Clonidine	50
d-Norpropoxyphene	12,5	EDDP	25
Promazine	12,5	4-Hydroxyphen-cyclidine	25
Promethazine	12,5	Levorphanol	25
Pentazocine	12,5	MDE	25
Phencyclidine	12,5	Meperidine	12,5
Tetrahydrozoline	250	d-Methamphet-amine	25
Mephentermine	12,5	l-Methamphet-amine	25
(1R, 2S) - (-)-Ephedrine	50	3,4-Methylendi-oxymethampheta-mine (MDMA)	50
Disopyramide	12,5	Thioridazine	25
KETAMINE (KET300)			
Ketamine	300	Benzphetamine	6,25
Dextromethorphan	600	(+) Chlorpheni-ramine	6,25
Methoxyphenamine	6,25	Clonidine	30
d-Norpropoxyphene	6,25	EDDP	15
Promazine	6,25	4-Hydroxyphen-cyclidine	15
Promethazine	6,25	Levorphanol	15
Pentazocine	6,25	MDE	15
Phencyclidine	6,25	Meperidine	6,25
Tetrahydrozoline	150	d-Methamphet-amine	15
Mephentermine	6,25	l-Methamphet-amine	15
(1R, 2S) - (-)-Ephedrine	30	3,4-Methylendi-oxymethampheta-mine (MDMA)	30
Disopyramide	6,25	Thioridazine	15
KETAMINE (KET100)			
Ketamine	100	Benzphetamine	2
Dextromethorphan	200	(+) Chlorpheni-ramine	2
Methoxyphenamine	2	Clonidine	10
d-Norpropoxyphene	2	EDDP	5
Promazine	2	4-Hydroxyphen-cyclidine	5
Promethazine	2	Levorphanol	5
Pentazocine	2	MDE	5
Phencyclidine	2	Meperidine	2
Tetrahydrozoline	50	d-Methamphet-amine	5
Mephentermine	2	l-Methamphet-amine	5
(1R, 2S) - (-)-Ephedrine	10	Thioridazine	5
Disopyramide	2	3,4-Methylendi-oxymethampheta-mine (MDMA)	10
Oxycodone (OXY100)			
Oxycodone	100	Hydromorphone	50
Oxymorphone	300	Naloxone	25
Levorphanol	50	Naltrexone	25
Hydrocodone	25		
Cotinine (COT 200)			
(-)-Cotinine	200	(-)-Nicotine	5
Cotinine (COT 100)			
(-)-Cotinine	100	(-)-Nicotine	2,5
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			300
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			100
Fentanyl (FYL 20)			
Alfentanyl	600	Buspirone	15
Fenfluramine	50	Fentanyl	100
Norfentanyl	20	Sufentanyl	50
Fentanyl (FYL 10)			
Alfentanyl	300	Buspirone	8
Fenfluramine	25	Fentanyl	50
Norfentanyl	10	Sufentanyl	25
Synthetic Marijuana (K2-50)			
JWH-018 5-Pentanoic acid	50	JWH-073 4-butanoic acid	50
JWH-018 4-Hydroxy-pentyl	400	JWH-018 5-Hydroxypentyl	500

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
JWH-073 4-Hydroxybuty	500		
Synthetic Marijuana (K2-30)			
JWH-018 5-Pentanoic acid	30	JWH-073 4-butanoic acid	30
JWH-018 4-Hydroxypentyl	250	JWH-018 5-Hydroxypentyl	300
JWH-073 4-Hydroxybuty	300		
6-mono-aceto-morphine (6-MAM)			
Codeine	10	Morphine	10
Ethylmorphine	200	Norcodeine	200
Hydrocodone	2	Normorphone	2
Hydromorphone	100	Oxycodone	1
Levorphanol	50	Oxymorphone	2
6-Monoacethylmorphine	10	Procaine	500
Morphine 3-β-D-glucuronide	30	Thebaine	200
(±) 3, 4-Methylenedioxyamphetamine (MDA 500)			
(±) 3,4-Methylenedioxy	500	Methoxyphenamine	6
amphetamine		D-Amphetamine	1
D,L-Amphetamine sulfate	300	Phentermine	1
L-Amphetamine	25	Maprotiline	50

EFFECT OF URINARY SPECIFIC GRAVITY

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50 % below and 50 % above cut-off levels respectively. The Multi-Drug Rapid Test Cup was tested in duplicate using fifteen 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 URINARY PH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50 % below and 50 % above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug Rapid Test Cup. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

CROSS-REACTIVITY

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Tramadol ,Ketamine ,Phencyclidine, Propoxyphene or Tricyclic Antidepressants, Oxycodone, Cotinine, EDDP, Fentanyl, Synthetic Marijuana, 6-mono-aceto-morphine, 3, 4-Methylenedioxyamphetamine and Ethyl-β-D-Glucuronide. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Cup at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds			
Acetophenetidin	Cortisone	Zomepirac	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline

Non Cross-Reacting Compounds			
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone
Atropine	bloidartsE-	Niacinamide	3-acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine	Isoxsuprine	d,l-Propanolol	

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Index of symbols			
REF	Article number		Temperature limitation
	Observe operating instructions	LOT	Batch number
IVD	In-vitro-diagnostic		Expiry date
	Manufacturer		Content sufficient for <n> tests
	Dangerous substances		Single use
	Protect from heat and sunlight		Attention
	Protect from moisture		
	Do not use, if package is damaged		
CE	CE marked according to IVD directive 98/79/EG		

ORDERING INFORMATION

REF C3 30605B-1	PZN 03200283	1 Test
REF C3 30605B	PZN 04031523	10 Teste
REF C3 306012-1	PZN 11138598	1 Test
REF C3 306012	PZN 11138581	10 Teste

IVD CE

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