QuickCheck Drug Screen Test Panel with Creatinine (Urine)

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

INTENDED USE

The QuickCheck Drug Screen 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	Analyte	Cut-off (ng/mL)
Amphetamine (AMP 1000)	d-Amphetamine	1,000
Barbiturates (BAR 300)	Secobarbital	300
Benzodiazepines (BZO 300)	Oxazepam	300
Buprenorphine (BUP 10)	Buprenorphine	10
Cocaine (COC 300)	Benzoylecgonine	300
Marijuana (THC 50)	11-nor-Δ9-THC-9 COOH	50
Methamphetamine (MET 1000)	d-Methamphetamine	1,000
Opiate (OPI 2000)	Morphine	2,000
Phencyclidine (PCP 25)	Phencyclidine	25
Oxycodone (OXY 100)	Oxycodone	100
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 100)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Fentanyl (FYL 20)	Fentanyl	20

Configurations of the QuickCheck Drug Screen Test Panel come with any combination of the above listed drug analytes with creatinine. 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 QuickCheck Drug Screen 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)

Amphetamine is a Schedule II controlled substance under Canada's Controlled Drugs and Substances Act 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 QuickCheck Drug Screen Test Panel yields a positive result when the concentration of amphetamines in urine exceeds cutoff level.

Barbiturates (BAR)

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 QuickCheck Drug Screen Test Panel yields a positive result when the concentration of barbiturates in urine exceeds cutoff level.

Benzodiazepines (BZO)

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 QuickCheck Drug Screen Test Panel yields a positive result when the concentration of benzodiazepines in urine exceeds cutoff level.

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.[7] While 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 QuickCheck Drug Screen Test Panel yields a positive result when the Buprenorphine in urine exceeds cutoff level.

Cocaine(COC)

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]

The QuickCheck Drug Screen Test Panel yields a positive result when the concentration of benzoylecgonine in urine exceeds cutoff level.

Marijuana (THC)

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 QuickCheck Drug Screen Test Panel yields a positive result when the concentration of THC-COOH in urine exceeds cutoff level.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The QuickCheck Drug Screen Test Panel yields a positive result when the methamphetamine in urine exceeds cutoff level.

Morphine/Opiate (OPI)

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 QuickCheck Drug Screen Test Panel yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

Phencyclidine (PCP)

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

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

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

The QuickCheck Drug Screen Test Panel yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).[1]

Oxycodone (OXY)

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

The QuickCheck Drug Screen Test Panel yields a positive result when oxycodone in urine exceeds 100 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]

2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)

Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound.[10] Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance. EDDP represents a better urine marker for methadone maintenance than unmetabolized methadone.

The QuickCheck Drug Screen Test Panel yields a positive result when the concentration of EDDP in urine exceeds cutoff level.

Fentanyl (FYL)

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 QuickCheck Drug Screen Test Panel yields a positive result when the concentration of fentanyl in urine exceeds cutoff level.

ADULTERATION

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

Creatinine is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[2] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine is a way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine levels may indicate dilute urine. Absence of creatinine (<5 mg/dl) is indicative of a specimen not consistent with human urine.

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 coloured 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 coloured line will not form in the test region.

A drug-positive urine specimen will not generate a coloured 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 coloured 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 pad contains anti-drug mouse monoclonal antibody and rabbit IgG. The test line contains the corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies.

CREATININE TEST REAGENT

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Creatinine	0.04%	99.96%

PRECAUTIONS
1. For healthcare professionals including professionals at point of care sites.
2. For in vitro diagnostic use only. The test panel should remain in the sealed pouch until use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test panel should be discarded according to federal, provincial and local regulations.
5. The test strip is not designed to test drugs before they are consumed. When used this way, the test strip may not test certain drugs, including fentanyl, even if present.

STORAGE AND STABILITY
Store as packaged in the sealed pouch at 2ºC to 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, dry, disposable 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.

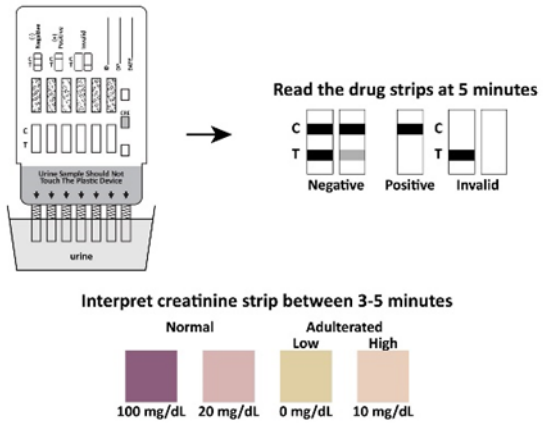
Specimen Storage
Urine specimens may be stored at 2ºC to 8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When testing with creatinine strip, storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing. To prevent tampering of the urine sample during transport to the laboratory and storage, the use of a security seal following collection is recommended. Security seal is available separately from Innovatek Medical Inc.

MATERIALS PROVIDED
- Drug Screen Test Panels
- Instruction For Use

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer
- Security Seal
- Urine Container

DIRECTIONS FOR USE
1. Donor provides urine specimen in a urine container.
2. If needed, the technician dates and initials the security seal and attaches the security seal over the urine container.
3. Allow the test panel, urine specimen (if stored), and/or controls to reach room temperature (15ºC to 30ºC) prior to testing. Remove the panel from the sealed pouch and use within one hour.
4. Label the test panel with patient / client name. Remove the cap.
5. With the arrow pointing towards 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.**
6. Replace the cap and place the test panel on a non-absorbent flat surface.
7. Start the timer and wait for the coloured line(s) to appear.
8. **Read the creatinine strip between 3-5 minutes** according to colour chart below. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and to recollect and retest with another specimen in case of any abnormal result for the creatinine strip.
9. **The drug strip result should be read at 5 minutes.** Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS
Please refer to the illustration below
NEGATIVE:*
A coloured line appears in the Control region (C) and coloured line appear in the Test region (T). This negative result means that the concentration in the urine sample is below the designated cut-off level for a particular drug tested.
***NOTE:** The shade of the coloured lines in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.
POSITIVE:
A coloured 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.



INTERPRETATION OF CREATININE TEST
(Please refer to the colour chart above)
Semi Quantitative results are obtained by visually comparing the reacted colour blocks on the creatinine strip to the printed colour blocks on the colour chart. No instrumentation is required. If the test pad colour matches that under "Normal" it indicates the urine specimen has not be adulterated.

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 QuickCheck Drug Screen 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.

CREATININE TEST LIMITATIONS
Normal creatinine level is between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

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.

PERFORMANCE CHARACTERISTICS
Accuracy
A side-by-side comparison was conducted using the QuickCheck Drug Screen Test Panel 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
QuickCheck Drug Screen Test Panel		Positive	Negative	
AMP 1000	Positive	103	3	98.1%
	Negative	2	142	97.9%
BAR 300	Positive	98	2	96.1%
	Negative	4	146	98.6%
BZO 300	Positive	121	1	98.4%
	Negative	2	126	99.2%
BUP 10	Positive	105	0	99.1%
	Negative	1	144	>99.9%
COC 300	Positive	111	3	98.2%
	Negative	2	134	97.8%
THC 50	Positive	92	3	97.9%
	Negative	2	153	98.1%
MET 1000	Positive	76	5	96.2%
	Negative	3	166	97.1%
OPI 2000	Positive	117	8	96.7%
	Negative	4	121	93.8%
PCP 25	Positive	85	5	92.4%
	Negative	7	153	96.8%
OXY 100	Positive	84	1	97.7%
	Negative	2	163	99.4%
EDDP 100	Positive	95	5	96.9%
	Negative	3	147	96.7%
FYL 20	Positive	29	1	96.7%
	Negative	1	92	98.9%

% Agreement with Commercial Kit

	AMP 1000	BAR 300	BZO 300	BUP 10	COC 300	THC 50
Positive Agreement	>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%
Total Results	>99.9 %	>99.9 %	>99.9 %	>99.9 %	>99.9%	>99.9%

	MET 1000	OPI 2000	PCP 25	OXY 100	EDDP 100	FYL 20
Positive Agreement	>99.9%	*	>99.9%	*	*	*
Negative Agreement	>99.9%	*	>99.9%	*	*	*
Total Results	>99.9%	*	>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 1000)

Amphetamine 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
1,250	10	1	9	2	8	2	8
1,500	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

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

BUPRENORPHINE (BUP 10)

Buprenorphine	n per	Site A		Site B		Site C	

conc. (ng/mL)	site	-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	8	2
12.5	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

MARIJUANA (THC 50)

11-nor-Δ^9-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

METHAMPHETAMINE (MET 1000)

Methamphetamine 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
1,250	10	1	9	2	8	1	9
1,500	10	0	10	0	10	0	10

MORPHINE/OPIATE (OPI 2000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
1,000	10	10	0	10	0	10	0
1,500	10	9	1	9	1	9	1
2,500	10	1	9	1	9	1	9
3,000	10	0	10	0	10	0	10

PHENCYCLIDINE (PCP 25)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	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

OXYCODONE (OXY 100)

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

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 (FYL 20)

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	7	3	9	1	8	2
25	10	1	9	2	8	1	9
30	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 1000		BAR 300		BZO 300		BUP 10		COC 300		THC 50	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	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
-25% Cut-off	26	4	27	3	27	3	26	4	26	4	26	4
Cut-off	15	15	16	14	15	15	14	16	13	17	14	16
+25% Cut-off	3	27	4	26	3	27	3	27	3	27	3	27
+50% Cut-off	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

Drug Concentration Cut-off Range	MET 1000		OPI 2000		PCP 25		OXY 100		EDDP 100		FYL 20	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	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
-25% Cut-off	27	3	27	3	25	5	27	3	26	4	27	3
Cut-off	16	14	14	16	15	15	15	15	15	15	14	16
+25% Cut-off	3	27	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
+300% Cut-off	0	30	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 QuickCheck Drug Screen Test Panel at 5 minutes.

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
AMPHETAMINE (AMP 1000)			
D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	1,000
BARBITURATES (BAR 300)			
Amobarbital	5,000	Alphenol	600
5,5-Diphenylhydantoin	8,000	Aprobarbital	500
Allobarbital	600	Butabarbital	200
Barbital	8,000	Butalbital	8,000
Talbutal	200	Butethal	500
Cyclopentobarbital	30,000	Phenobarbital	300
Pentobarbital	8,000	Secobarbital	300
BENZODIAZEPINES (BZO 300)			
Alprazolam	100	Bromazepam	900
a-hydroxyalprazolam	1,500	Chlordiazepoxide	900
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Flunitrazepam	200	Diazepam	300
(±) Lorazepam	3,000	Estazolam	6,000
RS-Lorazepam-glucuronide	200	Triazolam	3,000
Midazolam	6,000		
BUPRENORPHINE (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000
MARIJUANA (THC 50)			
Cannabinol	35,000	△8-THC	17,000
11-nor-△8-THC-9 COOH	30	△9-THC	17,000
11-nor-△9-THC-9 COOH	50		
METHAMPHETAMINE (MET 1000)			
ρ-Hydroxymeth-amphetamine	25,000	(±)-3,4-Methylenedioxy-methamphetamine	12,500
D-Methamphetamine	1,000		
L-Methamphetamine	20,000	Mephentermine	50,000
MORPHINE/OPIATE (OPI 2000)			
Codeine	2,000	Morphine	2,000
Ethylmorphine	3,000	Norcodeine	25,000
Hydrocodone	50,000	Normorphone	50,000
Hydromorphone	15,000	Oxycodone	25,000
Levorphanol	25,000	Oxymorphone	25,000
6-Monoacetylmorphine	3,000	Procaine	50,000
Morphine 3-β-D-glucuronide	2,000	Thebaine	25,000
PHENCYCLIDINE (PCP 25)			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
Oxycodone (OXY 100)			
Oxycodone	100	Hydromorphone	50,000
Oxymorphone	300	Naloxone	25,000
Levorphanol	50,000	Naltrexone	25,000
Hydrocodone	25,000		
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 100)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			100
Fentanyl (FYL 20)			
Fentanyl	20	Norfentanyl	>100,000
Cyclopro Fentanyl	500	(±)cis-3-Methylfentanyl	500
Butyl fentanyl	300	Valeryl Fentanyl	200
Methoxyacetyl-Fentanyl	40	Acetyl Fentanyl	40
Ocfentanil	200	4-Fluoro-isobutyryl Fentanyl	200
para-Fluorobutyryl fentanil (PBPF)	200	para-Fluorofentanil	100

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 QuickCheck Drug Screen Test Panel 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 QuickCheck Drug Screen Test Panel. 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, Methamphetamine, Morphine, Phencyclidine, Oxycodone, EDDP, Fentanyl. The following compounds show no cross-reactivity when tested with the QuickCheck Drug Screen Test Panel 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	Isoxsuprine	Sulfamethazine
l-Ascorbic acid	Digoxin	d,l-Propanolol	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone-3-acetate
Atropine	β-Estradiol	Niacinamide	
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		d,l-Propranolol	

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