BioTeke

Rx only

BioTeke®Multi-Drug Urine Test Cup

PLEASE READ ALL INFORMATION IN THE PACKAGE INSERT BEFORE USING THE TEST!

PRODUCT NAME

BioTeke® Multi-Drug Urine Test Cup

PACKAGE SPECIFICATION

1Test/Kit

INTENDED USE

BioTeke® Multi-Drug Urine Test Cup is a competitive binding, lateral flow immunochromatographic assay. It is a rapid drug test for the qualitative and simultaneous detection of drugs and drug metabolites in human urine. It is for **in vitro diagnostic use only. Prescription Use Only**. Drug test cut-off concentrations are listed below:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	Amphetamine	500
Phenobarbital (BAR)	Phenobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150
Fentanyl (FTY)	Fentanyl	1
Methylenedioxymethampheta mine (MDMA)	Methylenedioxymethamphet amine	500
Methamphetamine (MET)	Methamphetamine	500
Morphine (MOP/OPI)	Morphine	300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	50
Nortriptyline (TCA)	Nortriptyline	1000

BioTeke® Multi-Drug Urine Test Cup can be a single drug test cup or used for any combination of the above listed analytes. The test provides only preliminary test results. A more specific method must be used in order to obtain a confirmed result. GC/MS or LC/MS is the preferred method.

SUMMARY

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance a class of potent sympathomimetic agents with therapeutic applications. 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. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. Amphetamine is usually taken orally, intravenously, or by smoking. 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.

Phenobarbital (BAR)

Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Barbiturate could develop tolerance and physiological dependency and lead to its abuse.

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. Buprenorphine is used as a substitution treatment for opioid addicts. 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 drug has been abused via intravenous, sublingual, intranasal and inhalation routes.

Oxazepam (BZO)

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse.

Cocaine (COC)

Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. 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. Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours).

Fentanyl (FTY)

Fentanyl is a potent narcotic analgesic with rapid onset and short duration of action, and has been listed in management of United Nations “Single Convention of narcotic drug in 1961”. Fentanyl rapidly crosses the blood-brain barrier, producing fast and pronounced CNS effect, such as a heightened euphoria and respiratory depression. It is even more addictive than heroin. Fentanyl is much more potent than heroin, and tends to produce significantly worse respiratory depression.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine has street many names including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks, etc. It is a stimulant with hallucinogenic tendencies. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heart stoke. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2~3 hours.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. 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. 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.

Morphine (MOP)

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 analgesics reduce 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.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (Heroin, Vicodin, Percocet, Morphine). It is administered either orally, or by intravenous or intra-muscular injection. The duration of effect of methadone is 12~24 hours. 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. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylprryolidine), and EMDP (2- ethyl-5-methy -3, 3-diphenylpyrrolidine).

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 is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®.

In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinencesymptoms from chronic opiate (heroin, morphine) use. It is often used to alleviate or prevent the on set of opiate withdrawal of heroin and methadone. The drug is most often administered orally. Like other opiates, Oxycodone can lead to death when overdosed. Its major urinary excretion products are oxymorphone and noroxycodone.

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. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. Large doses of Phencyclidine can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine could develop tolerances and physiological dependency and lead to its abuse. Self-injurious behavior is one of the devastating effects of phencyclidine. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

Marijuana (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ9-THC-9-COOH.

Nortriptyline (TCA)

Nortriptyline is one of the Tricyclic Antidepressants, TCA 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.

TEST PRINCIPLE

This kit employs highly specific antibody-drug conjugates and immunochromatographic technology: the membrane's test region (T) is pre-coated with a drug-protein conjugate, the binding pad contains a colored-microsphere-antibody conjugate, and a red control line always appears in the control region (C) to confirm adequate sample volume and proper flow. During testing, urine is added directly to the test cup; if no free drug is present the antibody conjugate binds to the T-line conjugate and generates a red test line (negative result), whereas if drug saturates the antibody conjugate no line forms in the test region (positive result), with the C-line serving as the kit's internal control.

REAGENTS

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

WARNINGS AND PRECAUTIONS

- Read the user instructions before testing.
- For in vitro diagnostic use and prescription use only.
- Please use within the validity period.
- Do not use the test if its foil pouch is torn or damaged.
- Used the test as soon as possible after opening the package.
- Do not re-use. Discard after first use.
- The sample should be fresh urine. Contaminated or tainted sample may give false results.
- Read result at 5 minutes. Do not read the result after 10 minutes.
- All samples and the used test cup should be discarded according to federal, state and local regulations.
- Keep out of reach of children.

STORAGE CONDITIONS AND SHELF LIFE

Store as packaged in the sealed pouch at 35.6-86°F (2-30°C) up to the date of expiration. Keep away from direct sunlight, moisture and heat. Test cup should be used within 1 hour after opening the foil pouch. Do not use beyond the expiration date. The date of manufacture and expiration: See package label for details.

SAMPLE REQUIREMENTS

Have the patient urinate directly into the test cup provided, or collect the patient's urine in a clean, dry container. Urine collected at any time of day can be used for testing. Please perform the test immediately after urine collection.

MATERIALS

Materials required

· 1 Test cup

· 1 User instruction

Materials required but not provided

· Clean and dry container

· Watch, clock or timer

TEST PROCEDURE

Test should be performed at room temperature 59-86°F (15-30°C).

1. Tear the foil pouch open and take out the test cup.
2. Remove the test cup lid and add urine sample. Sample volume must exceed the minimum line.
3. Close and tighten the lid. Place the test cup on a flat surface and start timing. Then peel off the label for results.
4. Read result at 5~10 minutes. Do not read the result after 10 minutes.



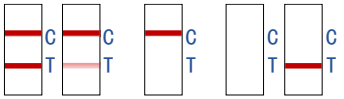
INTERPRETATION OF THE RESULT

Positive(+): A red line appears in the control (C) and no line in the test region (T). The result means that the subject may have recently used or abused the specific drug.

Negative(-): Red lines appear in both the control (C) and test region (T), meaning that the drug concentration is below the detectable level.

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

Invalid: If the control (C) lines do not appear, the test is considered invalid. An invalid test result means that an error has occurred and the result cannot be interpreted. You will need to retest using a new test cup.



A preliminary positive test result does not always mean that a person took illegal drugs. A negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

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 and correct procedural technique. Control standards are not supplied with this kit. 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. Quality control should be performed in accordance with federal, state, and local regulations.

LIMITATIONS

- The test provides a qualitative preliminary result only. Confirmed results must be obtained in lab for more advanced testing, such as GC/MS or LC/MS.
- Incorrect results may be obtained from procedural errors or interfering substance in the sample.
- Negative results can be obtained when drug is present but below the cut-off level of the test.
- Adulterants, such as bleach and/or alum, in urine samples may produce incorrect results.
- A positive result does not indicate intoxication, administration route or concentration in urine.
- The test does not indicate the frequency of drug use or distinguish between certain foods and medicines.
- By itself, this test will not confirm if someone used a drug of abuse. These types of tests may incorrectly detect the presence of a drug of abuse when the person has consumed certain foods, medicines, diet plan drugs, or nutritional supplements. These are just some examples of the types of things that can cause a false result and there may be others as well. In order to show if someone used a drug of abuse, you will need to send the urine sample to a laboratory to have a second test, called a confirmation test, performed. The cost of the additional testing is not included in the purchase price of this screening test kit

PERFORMANCE CHARACTERSTICS

Precision/ Reproducibility

The study was carried out for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cutoff and -100% cutoff. Samples were prepared by spiking target drugs in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test cups. The results as follows:

Test drug	Cut-off range	Results (Negative/Positive)		
		Lot 1	Lot 2	Lot 3
AMP	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	49-/1+	49-/1+	49-/1+
	cutoff	25-/25+	22-/28+	27-/23+
	+25% cutoff	0-/50+	0-/50+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
BAR	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	29-/21+	26-/24+	27-/23+
	+25% cutoff	1-/49+	0-/50+	1-/49+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
BUP	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	30-/20+	28-/22+	28-/22+
	+25% cutoff	2-/48+	1-/49+	1-/49+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
BZO	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	26-/24+	24-/26+	23-/27+
	+25% cutoff	0-/50+	0-/50+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
COC	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	27-/23+	26-/24+	28-/22+
	+25% cutoff	1-/49+	0-/50+	1-/49+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+

FTY	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	29-/21+	26-/24+	24-/26+
	+25% cutoff	2-/48+	1-/49+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
MDMA	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	25-/25+	27-/23+	28-/22+
	+25% cutoff	0-/50+	1-/49+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
MET	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	24-/26+	25-/25+	27-/23+
	+25% cutoff	1-/49+	0-/50+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
MOP	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	25-/25+	25-/25+	25-/25+
	+25% cutoff	0-/50+	0-/50+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
MTD	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	49-/1+	50-/0+	50-/0+
	cutoff	24-/26+	22-/28+	25-/25+
	+25% cutoff	0-/50+	0-/50+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
OXY	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	24-/26+	27-/23+	25-/25+
	+25% cutoff	0-/50+	0-/50+	1-/49+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
PCP	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	27-/23+	28-/22+	26-/24+
	+25% cutoff	1-/49+	0-/50+	2-/48+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
THC	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	49-/1+	48-/2+	49-/1+
	cutoff	21-/29+	22-/28+	24-/26+
	+25% cutoff	0-/50+	0-/50+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+
TCA	-100% cutoff	50-/0+	50-/0+	50-/0+
	-75% cutoff	50-/0+	50-/0+	50-/0+
	-50% cutoff	50-/0+	50-/0+	50-/0+
	-25% cutoff	50-/0+	50-/0+	50-/0+
	cutoff	23-/27+	25-/25+	24-/26+
	+25% cutoff	0-/50+	0-/50+	0-/50+
	+50% cutoff	0-/50+	0-/50+	0-/50+
	+75% cutoff	0-/50+	0-/50+	0-/50+
	+100% cutoff	0-/50+	0-/50+	0-/50+

Accuracy

About 80 clinical urine samples with were analyzed by LC-MS/MS values and tested by BioTeke® Multi-Drug Urine Test Cup. Each test was performed by three operators. Results were as follows:

Test drug	BioTeke® Multi-Drug Urine Test Cup Result		LC/MS Result		Agreement with LC-MS/MS
			Above cut-off (Positive)	Lower cut-off (Negative)	
AMP	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
BAR	Operator A	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator B	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator C	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
BUP	Operator A	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
BZO	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator B	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator C	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
COC	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator B	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator C	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
FTY	Operator A	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator B	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
	Operator C	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
MDMA	Operator A	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator B	Positive	38	0	38/40=95%
		Negative	2	40	40/40=100%
		Accuracy	(38+40)/80*100%=97.5%		
	Operator C	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
MET	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
MOP	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator B	Positive	38	1	38/40=95%
		Negative	2	39	39/40=97.5%
		Accuracy	(38+39)/80*100%=96.25%		
	Operator C	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
MTD	Operator A	Positive	40	1	40/40=100%
		Negative	0	39	39/40=97.5%
		Accuracy	(40+39)/80*100%=98.75%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	39	1	39/40=97.5%

		Negative	1	39	39/40=97.5%
		Accuracy	(39+39)/80*100%=97.5%		
OXY	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	40	2	40/40=100%
		Negative	0	38	38/40=95%
		Accuracy	(40+38)/80*100%=97.5%		
PCP	Operator A	Positive	38	0	38/40=95%
		Negative	2	40	40/40=100%
		Accuracy	(38+40)/80*100%=97.5%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
THC	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
TCA	Operator A	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		
	Operator B	Positive	39	0	39/40=97.5%
		Negative	1	40	40/40=100%
		Accuracy	(39+40)/80*100%=98.75%		
	Operator C	Positive	40	0	40/40=100%
		Negative	0	40	40/40=100%
		Accuracy	(40+40)/80*100%=100%		

Analytical Specificity

The following table lists compounds (ng/mL) above which the test identified positive results at a read time of 5 minutes:

Drug/ Cutoff	Compound	Concentration (ng/mL)	Cross-Reactivity
AMP 500	Amphetamine	500	100%
	(+/-)-Methylenedioxyamphetamine(MDA)	50	1000%
	(+/-)3,4-Methylenedioxyethylamphetamine(MDEA)	100000	0.50%
	(+/-)3,4-Methylenedioxymethamphetamine(MDMA)	1000	50%
	R (-)-Amphetamine	500	100%
	Diethylstilbestrol	500	100%
	Methamphetamine	>100000	<0.5%
	Ephedrine Hydrochloride	>100000	<0.5%
	Pseudoephedrine Hydrochloride	>100000	<0.5%
	Hydroxyamphetamine	>100000	<0.5%
	D,L-Amphetamine	1000	50%
	D-Amphetamine	2000	25%
	L-Amphetamine	500	100%
	Phentermine	>100000	<0.5%
	β-Phenylethylamine	>100000	<0.5%
	Tyramine	>100000	<0.5%
	p-Hydroxynorephedrine	>100000	<0.5%
	D,L-Norephedrine	>100000	<0.5%
	p-Hydroxyamphetamine	>100000	<0.5%
	D-Methamphetamine	>100000	<0.5%
	L-Methamphetamine	>100000	<0.5%
	Phenylpropanolamine	>100000	<0.5%
	Benzphetamine	>100000	<0.5%
	L-Ephedrine	>100000	<0.5%
	L-Epinephrine	>100000	<0.5%
	D,L-Epinephrine	>100000	<0.5%
BAR 300	Phenobarbital	300	100%
	Barbital	300	100%
	Secobarbital	300	100%
	Pentobarbital	2000	15%
	Alphenal	300	100%
	Amobarbital	300	100%
	Aprobarbital	500	60%
	Butabarbital	>100000	<0.3%
	Butethal	300	100%
	Cyclopentobarbital	500	60%
	Butalbital	>100000	<0.3%
BUP 10	Buprenorphine	10	100%
	Buprenorphine-3-D-Glucuronide	20	50%
	Norbuprenorphine	20	50%
	Morphine	>100000	<0.01%
	Oxymorphone	>100000	<0.01%
	Hydromorphone	>100000	<0.01%
	Codeine Phosphate	>100000	<0.01%
	Norbuprenorphine-3-D-Glucuronide	1000	1%
	Nalorphine	>100000	<0.01%
BZO 300	Oxazepam	300	100%
	Alprazolam	200	150%
	Chlordiazepoxide	300	100%
	Clobazam	200	150%
	Clonazepam	200	150%
	Diazepam	300	100%
	Estazolam	100	300%
	Flunitrazepam	300	100%
	Midazolam	10000	3%
	Nitrazepam	200	150%
	Nordiazepam	200	150%
	Temazepam	100	300%
	Triazolam	300	100%
	Flurazepam	300	100%
	Lorazepam	10000	3%
	Lormetazepam	100	300%
	a-Hydroxyalprazolam	>100000	<0.3%
	Bromazepam	>100000	<0.3%
	Clorazepate Dipotassium	300	100%
	Desalkylflurazepam	>100000	<0.3%
	D,L-Lorazepam	>100000	<0.3%
	Norchlordiazepoxide	300	100%
	R,S-Lorazepam glucuronide	>100000	<0.3%
	Demoxepam	>100000	<0.3%
	Delorazepam	>100000	<0.3%
COC 150	Benzoylecgonine	150	100%
	Cocaine Hydrochloride	10000	1.50%
	Ecgonine methyl ester	>100000	<0.15%
	Cocaethylene	>100000	<0.15%
	Ecgonine	>100000	<0.15%
	Norcocaine	>100000	<0.15%
FTY 1	Fentanyl	1	100%
	Acetyl fentanyl	1	100%
	Sufentanil	10	10%
	Alfentanil	5000	0.02%
	Remifentanil	>100000	<0.001%
	Norfentanyl	>100000	<0.001%
	Acrylfentanyl	>100000	<0.001%
	ω-1-Hydroxyfentanyl	>100000	<0.001%
	Isobutyryl fentanyl	>100000	<0.001%
	Ocfentanil	5	20%
	Butyryl fentanyl	>100000	<0.001%
	Furanyl fentanyl	>100000	<0.001%
	Valeryl fentanyl	>100000	<0.001%
	(±) β-hydroxythiofentanyl	5	20%
	4-Fluoro-isobutyrylfentanyl	>100000	<0.001%
	Para-fluorobutyryl fentanyl	5	20%
	Para-fluoro fentanyl	5	20%
	(±)-3-cis-methyl fentanyl	>100000	<0.001%
	Carfentanil	>100000	<0.001%
	Despropionyl fentanyl (4-ANPP)	>100000	<0.001%
	Acetyl norfentanyl	>100000	<0.001%
	Norcarfentanil	>100000	<0.001%
	6-Acetyl morphine	>100000	<0.001%
	Amphetamine	>100000	<0.001%
	Buprenorphine	>100000	<0.001%
	Buprenorphineglucuronide	>100000	<0.001%
	Codeine	>100000	<0.001%
	Dextromethorphan	>100000	<0.001%
	Dihydrocodeine	>100000	<0.001%
	EDDP	>100000	<0.001%
	EMDP	>100000	<0.001%
	Fluoxetine	>100000	<0.001%
	Heroin	>100000	<0.001%
	Hydrocodone	>100000	<0.001%
	Hydromorphone	>100000	<0.001%
	Ketamine	>100000	<0.001%
	Levorphanol	>100000	<0.001%
	Meperidine	>100000	<0.001%
	Methadone	>100000	<0.001%
	Morphine	>100000	<0.001%
	Morphine-3-glucuronide	>100000	<0.001%
	Naloxone	>100000	<0.001%
	Naltrexone	>100000	<0.001%
	Norbuprenorphine	>100000	<0.001%
	Norcodeine	>100000	<0.001%
	Norketamine	>100000	<0.001%
	Normeperidine	>100000	<0.001%
	Normorphine	>100000	<0.001%
	Noroxycodone	>100000	<0.001%
	Oxycodone	>100000	<0.001%
	Oxymorphone	>100000	<0.001%
	Pentazocine (Talwin)	>100000	<0.001%
	Pipamperone	>100000	<0.001%
	Risperidone	>100000	<0.001%
	Tapentadol	>100000	<0.001%

	Thioridazine	>100000	<0.001%
	Tilidine	>100000	<0.001%
	Tramadol	>100000	<0.001%
	Tramadol-O-Desmethyl	>100000	<0.001%
	Tramadol-N-Desmethyl	>100000	<0.001%
MDMA 500	(±)3,4-Methylenedioxymethamphetamine(MDMA)	500	100%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	1000	50%
	(+/-)-Methylenedioxyamphetamine(MDA)	1000	50%
	Amphetamine	1000	50%
	R (-)-Amphetamine	1000	50%
	Methamphetamine	10000	5%
	Ephedrine Hydrochloride	10000	5%
	Pseudoephedrine Hydrochloride	>100000	<0.5%
	L-Methamphetamine	>100000	<0.5%
	d-methamphetamine	10000	5%
	d-amphetamine	>100000	<0.5%
	l-amphetamine	1000	50%
	d,l-Amphetamine	5000	10%
	d,l-Methamphetamine	10000	5%
	Phentermine	>100000	<0.5%
	Phenylephrine	>100000	<0.5%
MET 500	Methamphetamine	500	100%
	(±)3,4-Methylenedioxymethamphetamine(MDMA)	1000	50%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	10000	5%
	(+/-)-Methylenedioxyamphetamine(MDA)	10000	5%
	Methoxyphenamine Hydrochloride	>100000	<0.5%
	Chloroquine	10000	5%
	Amphetamine	1000	50%
	R (-)-Amphetamine	1000	50%
	Ephedrine Hydrochloride	10000	5%
	Pseudoephedrine Hydrochloride	>100000	<0.5%
	D-Methamphetamine	500	100%
	L-Methamphetamine	>100000	<0.5%
	Fenfluramine	>100000	<0.5%
	p-Hydroxymethamphetamine	>100000	<0.5%
	D,L-Methamphetamine	1000	50%
	β-Phenylethylamine	>100000	<0.5%
	Mephetermine	>100000	<0.5%
	L-Amphetamine	1000	50%
	D-Amphetamine	>100000	<0.5%
	D,L-Amphetamine	1000	50%
	Trimethobenzamide	>100000	<0.5%
	l-phenylephrine	>100000	<0.5%
	(1R,2S)-(-)-Ephedrine	>100000	<0.5%
	Procaine hydrochloride	>100000	<0.5%
	Phentermine	>100000	<0.5%
MOP 300	Morphine	300	100%
	6-acetylmorphine	300	100%
	Codeine Phosphate	250	120%
	EthylMorphine	200	150%
	Heroin	500	60%
	Hydrocodone	1000	30%
	Levorphanol tartrate	1500	20%
	Morphine-3-β-d-glucuronide	1000	30%
	Thebaine	10000	3%
	Morphine-6-β-D-glucuronide	1000	30%

	Dihydrocodeine	>100000	<0.3%
	Hydromorphone	>100000	<0.3%
	Nalorphine hydrochloride	1000	30%
	s-Monoacetylmorphine	500	60%
	6-Monoacetylmorphine (6-MAM)	500	60%
	Codeine-6-β-D-glucuronide	>100000	<0.3%
	6-Acetylcodeine	>100000	<0.3%
	Normorphine	>100000	<0.3%
	Oxycodone	>100000	<0.3%
	Oxymorphone	>100000	<0.3%
	Norcodeine	>100000	<0.3%
	Procaine hydrochloride	>100000	<0.3%
	Norpropoxyphene	>100000	<0.3%
MTD 300	Methadone	300	100%
	EDDP	>100000	<0.3%
	EMDP	>100000	<0.3%
	Doxylamine	>100000	<0.3%
	EsomeprazoleMagnesium	10000	3%
	LAAM	>100000	<0.3%
	Alpha Methadol	>100000	<0.3%
	Disopyramide	>100000	<0.3%
	Pheniramine	>100000	<0.3%
OXY 100	Oxycodone	100	100%
	Hydrocodone	50000	0.20%
	Hydromorphone	25000	0.40%
	Naloxone Hydrochloride	>100000	<0.1%
	Naltrexone Hydrochloride	>100000	<0.1%
	Oxymorphone	100	100%
	Noroxycodone	1000	10%
	Noroxymorphone	25000	0.40%
	Dihydrocodeine	12500	0.80%
	Codeine Phosphate	100000	0.10%
	Morphine	>100000	<0.1%
	Buprenorphine	>100000	<0.1%
	Ethyl Oxycodone	>100000	<0.1%
	Levorphanol tartrate	>100000	<0.1%
	Oxymorphone-3β-D-glucuronide	>100000	<0.1%
	Acetylmorphine	>100000	<0.1%
	Ethylmorphine	>100000	<0.1%
	Thebaine	>100000	<0.1%
	6-acetylmorphine	>100000	<0.1%
PCP 25	Phencyclidine	25	100%
	Pheniramine	50000	0.05%
	4-Hydroxyphencyclidine	>100000	<0.025%
TCA 1000	Nortriptyline	1000	100%
	Amitriptyline Hydrochloride	1500	66.70%
	Chlorphenamine Maleate	>100000	<1%
	Clomipramine Hydrochloride	1000	100%
	Cyclobenzaprine Hydrochloride	>100000	<1%
	Desipramine	300	333.30%
	Doxepin Hydrochloride	10000	10%
	Duloxetine Hydrochloridum	>100000	<1%
	Imipramine Hydrochloride	500	200%
	Desmethylimipramine Hydrochloride	250	400%
	Chlorpromazine Hydrochloride	>100000	<1%
	Maprotiline Hydrochloride	>100000	<1%
	Promethazine Hydrochloride	50000	2%
	Norclomipramine	>100000	<1%
	Nordoxepine	>100000	<1%

	Promazine	>100000	<1%
	Trimipramine	>100000	<1%
	Maprotiline	>100000	<1%
THC 50	11-nor-9-Carboxy-Δ9-THC	50	100%
	(±)-11-nor-9-Carboxy-Δ9-THC	50	100%
	Δ8-Tetrahydrocannabinol	>100000	<0.05%
	Δ9-Tetrahydrocannabinol	1000	5%
	Cannabinol	10000	0.50%
	Cannabidiol	>100000	<0.05%
	11-nor-Δ8-THC-9-COOH	>100000	<0.05%
	11-nor-Δ9 -THC -carboxyglucuronide	100	50%
	11-hydroxy-Δ9 -Tetrahydrocannabinol	>100000	<0.05%

Interference

A study was conducted to determine the interference of the test with compounds in either drug-free urine target drugs urine with concentrations at 50% below and 50% above each corresponding cutoff. The following compounds show no cross-reactivity when tested with the BioTeke® Multi-Drug Urine Test Cup at a concentration of 100μg/ml or specified concentrations.

Ranitidine Hydrochloride	Sertraline Hydrochloride	Nitroglycerin
Gatifloxacin	Diflunisal	Nordoxepin
Naloxone Hydrochloride	Fenofibrate	Norethindrone
Cefalexin	Aripiprazole	Norfentanyl
Benzylpenicillin	Propranolol Hydrochloride	O-Hydroxyhippuric acid
Ibuprofen	Citalopram Hydrobromide	Albumin (100mg/dL)
Aspirin	Lisinopril	Albuterol sulfate (Proair HFA)
Caffeine	Quetiapine Fumarate	Alpha Methadol
Atropine Sulfate	Apomorphine Hydrochloride	Aminophylline
Bilirubin	Estrone	Aminopyrine
Dopamine Hydrochloride	Creatine	Ascorbic acid
Salicylic Acid	Desloratadine	Benzilic acid
Ampicillin	Baclofen	Benzphetamine
Creatinine	Olanzapine	Boric Acid
Loratadine	Pregabalin	Cannabidiol
γ-Cyclodextrin	4-(methylamino)-antipyrine	Carfentanil
Urea	Cortisone	Cephalexin
Vitamin C	Chlorothiazide	Chloralhydrate
Oxalic Acid	D-Glucoseanhydrous	Chloroquine
Benzoic Acid	Cholesterol	Chlorpheniramine
Methoxyphenamine Hydrochloride	5－Hydroxytryptamine Hydrochloride	Doxepin (except TCA test)
Digoxin	Chloramphenicol	Levothyroxine Sodium
Paracetamol	Tetracycline	Ecgonine methyl ester
Metformin Hydrochloride	Erythromycin	EMDP
Chlorphenamine Maleate	Clarithromycin	Ephedrine (except MDMA and MET test)
Diphenhydramine Hydrochloride	Amoxicillin	Esomeprazole Magnesium (except MTD test)
Clonidine Hydrochloride	Cefradine	Ethanol
Levonorgestrel	Ciprofloxacin	Fenoprofen
Metoprolol Tartrate	Levofloxacin	Galactose
Phenacetin	Phenoxymethylpenicillin	Gamma Globulin (500mg/dL)
Nicotinamide	Rifampicin	Gentisic acid
Vitamin B6	Azithromycin	Glucose (3000mg/dL)
Theophylline	Tyrosine	Hemoglobin
Perphenazine	Tryptophan	Hydroxytyramine
Carbamazepine	Pethidine Hydrochloride	Isoproterenol
Hydrocortisone	Papaverine Hydrochloride	L-Ephedrine

Epinephrine	Noscapine	L-Epinephrine
Fluphenazine Hydrochloride	Tramadol Hydrochloride	LAAM HCl
Isoprenaline Hydrochloride	Ketamine Hydrochloride	L-Thyroxine
Norepinephrine Bitartrate	Paliperidone	Octopamine
Estradiol	Quinine Sulfate	Oxolinic acid
Metronidazole	Mifepristone	Penicillin-G
Naproxen	Phenelzine	Penicillin-V Potassium
Prednisone	Sildenafil Citrate	Phentermine
Dextromethorphan Hydrobromide	Aspartame	Promethazine (except TCA test)
Sulpiride	Nalidixic Acid	Propoxyphene
Phenylpropanolamine Hydrochloride	Isoxsuprine Hydrochloride	Pseudoephedrine
Verapamil Hydrochloride	Atomoxetine Hydrochloride	Riboflavin
Desoxycortone Acetate	Duloxetine Hydrochloride	Sulfamethazine
Oxymetazoline Hydrochloride	Doxylamine	Tetrahydrocortisone 3-β-D-glucuronide
Maprotiline Hydrochloride	Interferonalpha	Tetrahydrocortisone 3-acetate
Phenylephrine Hydrochloride	Zanamivir	Conjugated Estrogens
Hydralazine Hydrochloride	Ribavirin	Cotinine
Gemfibrozil	Oseltamivir	Cyclobenzaprine
Loperamide Hydrochloride	Peramivir	D-Pseudoephedrine
Hydrochlorothiazide	Lopinavir	D,L-Epinephrine
Captopril	Tetrahydrozoline	D,L-Isoproterenol
Clozapine	Arbidol	D,L-Octopamine
Salbutamol Sulfate	L-Phenylephrine	D,L-Propranolol
Sulindac	Ceftriaxone	D,L-Tryptophan
Ketoprofen	Meropenem	D,L-Tyrosine
Nifedipine	Tobramycin	Delorazepam
Lidocaine Hydrochloride	Phenethylamine	Deoxycorticosterone
Thioridazine Hydrochloride	Beclomethasone	Diclofenac sodium
Omeprazole	Dexamethasone	Magnesium
Vitamin B2	Flunisolide	Meperidine
Vitamin B1	Triamcinolone acetonide	Meprobamate
Procaine Hydrochloride	Budesonide	Methapyrilene
Triamterene	Mometasone	Methaqualone
Nicotinic Acid	Fluticasone	N-Acetylprocainamide
Chlorpromazine Hydrochloride	Histamine Hydrochloride	NaCl
Labetalol Hydrochloride	DL-Menthol	Naltrexone hydrochloride
Aminophenazone	Benzocaine	Niacinamide
Fluoxetine Hydrochloride	Mupirocin	Nicotine
Venlafaxine Hydrochloride	3-Hydroxytyramine	Thiamine
Furosemide	Acetaminophen	Trifluoperazine
Risperidone	Acetone (1000mg/dL)	Trimethobenzamide
Atorvastatin Calcium	Acetophenetidin	Trimethoprim
Simvastatin	Acetylsalicylic acid	Tyramine
Telmisartan	Acyclovir	Uric acid
Gabapentin	Disopyramide	Valproic acid (250ug/ml)
Zaleplon	DL-Tryptophan	Zomepirac
Bupropion Hydrochloride	DL-Tyrosine	β-Estradiol
Boric Acid (1%)	Metronidazole (300μg/mL)	Oxalic acid (100 mg/dL)
Ethanol (1%)	NaCl (4000mg/dL)	Urea (2000mg/dL)

Effect of Urinary Specific Gravity

Urine samples of normal, high, and low specific gravity ranges 1.000-1.035 were spiked with drugs at 50% below and 50% above cut-off levels respectively. Each sample was tested by the test device. 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 4 to 9 and spiked with drugs at 50% below and 50% above cut-off levels. Each sample was tested by the test device. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

REFERENCE

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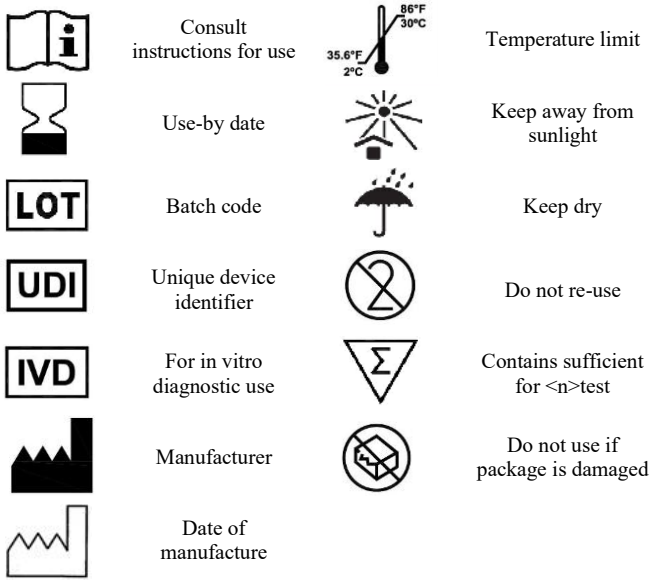
SYMBOLS



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Revision date: 2026-09-10
Edition: A3

图纸名称	说明书-英文	文件号	RD2506-14-040401-101-A0	材质	双胶纸
尺寸	A4	颜色	见图纸		
设计/日期		审核/日期		批准/日期	