



浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co.,LTD

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## STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

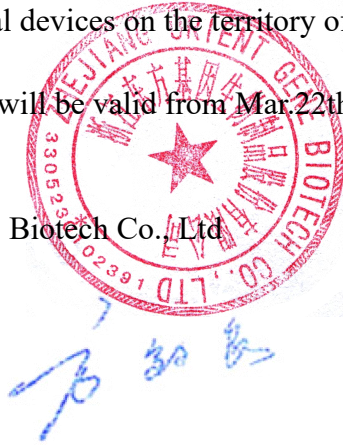
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co.,Ltd

General Manager:

Date:2024/3/22



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# Certificate

No. Q5 092305 0001 Rev. 02

**Holder of Certificate:** **Zhejiang Orient Gene Biotech Co., Ltd.**  
3787#, East Yangguang Avenue, Dipu Street Anji  
313300 Huzhou, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_092305_0001_Rev.02)

**Report No.:** SH2398804

**Valid from:** 2024-03-17

**Valid until:** 2027-03-16

**Date,** 2024-03-01

Christoph Dicks  
Head of Certification/Notified Body



Product Service

# Certificate

No. Q5 092305 0001 Rev. 02

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Zhejiang Orient Gene Biotech Co., Ltd.**  
3787#, East Yangguang Avenue, Dipu Street Anji, 313300  
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG054  
Version 1.0



# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** *Zhejiang Orient Gene Biotech Co., Ltd*

**Legal Manufacturer Address:** *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products  
Product Name and Model(s)

One Step Multi-Drug Screen Test Dip Card (Urine)	GBDUA-1X4
One Step Multi-Drug Screen Test Cassette (Urine)	GBDOA-1X5
One Step Multi-Drug Screen Test Cup (Urine)	GBDUA-1X6

Classification: *Other*  
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

**EC Representative's Name:** Shanghai International Holding Corp. GmbH (Europe)

**EC Representative's Address:** Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

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Name of authorized signatory: Joyce Pang  
Position held in the company: Vice-President

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浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG060  
Version 1.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** *Zhejiang Orient Gene Biotech Co., Ltd*

**Legal Manufacturer Address:** *3787#, East Yangguang Avenue, Dipu Street,  
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products  
Product Name and Model(s)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

**Classification:** *Other*  
**Conformity assessment route:** *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

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Date Signed: November 28, 2017

Name of authorized signatory: Joyce Pang  
Position held in the company: Vice-President

# One Step Multi-Drug Screen Cassette Test (Urine)

## Package Insert



Package insert for testing of any combination of the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypropylvalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants.

*A rapid, one step screening test for the simultaneous, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypropylvalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants and the metabolites in human urine.*

*For healthcare professional in vitro diagnostic use only.*

### INTENDED USE

Urine based Drug tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The **One Step Multi-Drug Screen Cassette Test (Urine)** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs, drug metabolites and alcohol at the following cut-off concentrations in urine:<sup>1</sup>

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Amphetamine (AMP)	D-Amphetamine	500
Amphetamine (AMP)	D-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Barbiturates (BAR)	Secobarbital	200
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO)	Oxazepam	200
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC )	Benzoylcegonine	300
Cocaine (COC )	Benzoylcegonine	150
Cotinine (COT)	Cotinine	200
MDMA (Ecstasy)	D,L-3,4-Methylenedioxyamphetamine (MDMA)	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	300
Fentanyl (FEN)	Fentanyl	300
Fentanyl (FEN)	Fentanyl	200
Fentanyl (FEN)	Fentanyl	100
Fentanyl (FEN)	Norfentanyl	20
Ketamine (KET)	Ketamine	1,000
Ketamine (KET)	Ketamine	100
Lysergic acid diethylamide (LSD)	D-lysergic acid diethylamide	20
Marijuana (THC )	11-nor- $\Delta^9$ -THC-9 COOH	50
Marijuana (THC )	11-nor- $\Delta^9$ -THC-9 COOH	25
Marijuana (THC )	11-nor- $\Delta^9$ -THC-9 COOH	20
Methadone (MTD)	Methadone	300
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	100
Methamphetamine (MET, mAMP)	D-Methamphetamine	1,000
Methamphetamine (MET, mAMP)	D-Methamphetamine	500
Methamphetamine (MET, mAMP)	D-Methamphetamine	300
Methaqualone (MQL)	Methaqualone	300
Methylenedioxypropylvalerone	3,4-Methylenedioxypropylvalerone	1,000

(MDPV)		
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Morphine (MOP 300)	Morphine	300
Morphine (OPI, MOP 2000 )	Morphine	2,000
Oxycodone (OXY )	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50
K2 Synthetic Cannabinoid	JWH-073/JWH-018	25
Tramadol (TRA)	Tramadol	200
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Alcohol (ALC)	Ethanol	>0.04% B.A.C

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

**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 used.**

### SUMMARY

#### AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

#### BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

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

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.

#### 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 the Benzodiazepines in the urine is 3-7 days.

#### BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause

dependency. Subutex® and a Buprenorphine/Naloxone combination product, Suboxone® are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

#### COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylcegonine.<sup>1,2</sup> Benzoylcegonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.<sup>2</sup>

#### COTININE (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.<sup>1</sup> While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.<sup>2</sup> Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

#### MDMA (ECSTASY)

Methylenedioxyamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlander, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

#### ETHYL GLUCURONIDE (ETG)

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol alcohol. The presence of EtG in the urine can be used to detect recent alcohol consumption, even after the ethanol alcohol is no longer measurable. Consequently, the presence of EtG in the urine is a definitive indicator that alcohol has been ingested. Traditional laboratory practices typically measure the amount of alcohol present in the body. Depending on the amount of alcohol that has been consumed, this method usually reveals alcohol ingestion within the past few hours.

The presence of EtG in the urine, on the other hand, demonstrates that ethanol alcohol was ingested within the past three or four days, or roughly 80 hours after the ethanol alcohol has been metabolized by the body. As a result, it can be determined that a urine alcohol test employing EtG is a more accurate indicator of the recent consumption of alcohol as opposed to simply measuring for the existence of ethanol alcohol.

#### FENTANYL (FEN)

Fentanyl is a synthetic opioid. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. The Fentanyl drug is approximately 100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg. of morphine or 75 mg. of meperidine in analgesic activity. The Fentanyl drug is a potent narcotic analgesic with rapid onset and short duration of action. Historically, the fentanyl drug has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl drugs first appeared in the mid-1970s. Because the effects of the fentanyl drug last for only a very short time, it is even more addictive than heroin. Regular users may become addicted very quickly. The Fentanyl drug is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. Overdose of the fentanyl drug has caused death. In the United States, the fentanyl drug is classified as a Schedule II controlled substance.

#### KETAMINE (KET)

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP ('Angel Dust'). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is

most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately a 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

#### **LYSERGIC ACID DIETHYLAMIDE (LSD)**

D-lysergic acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram. Compared to other hallucinogenic substances, LSD is 100 times more potent than psilocybin and psilocin and 4,000 times more potent than mescaline. The dosage level that will produce a hallucinogenic effect in humans generally is considered to be 25 micrograms. Over the past several years, the potency of LSD obtained during drug law enforcement operations has ranged between 20 and 80 micrograms per dosage unit. The Drug Enforcement Administration (DEA) recognizes 50 micrograms as the standard dosage unit equivalency.

#### **MARIJUANA (THC)**

THC ( $\Delta^9$ -tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it 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 smoking marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid ( $\Delta^9$ -THC-COOH).

#### **METHADONE (MTD)**

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of Morphine dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

#### **EDDP**

EDDP is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate-dependent patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The tampering of specimens by spiking the urine with methadone can be prevented. Also, renal clearance of EDDP is not affected by urinary pH; therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone test. Methadone is an unusual drug in a sense that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure. Thus, they are very difficult to detect with immunoassays targeted to the native compound. 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.

#### **METHAMPHETAMINE (MET, mAMP)**

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

#### **METHAQUALONE (MQL)**

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally

encountered in illicit form, and is also available in European countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

#### **METHYLENEDIOXYPYROVALERONE (MDPV)**

Bath salts', a form of designer drugs, also promoted as 'plant food' or 'research chemicals', is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised as "legal" highs. The technical term for 'bath salts' is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of 'bath salts'. In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinone, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada. Established as one of the main ingredients for 'bath salts', among other synthetic stimulants like Mephedrone, Methyone, Butylone and Methedrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulant.

While synthetic stimulants appear to affect users in ways similar to amphetamines, ecstasy and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. These negative effects have resulted in an increase of ER visits and hospitalizations, severe psychotic and violent episodes, self-inflicted wounds, suicide and an alarming increase in abuse-related deaths. U.S. Poison Control and National Drug Intelligence have all issued health warnings, noting nationwide emergency room visits related to these drugs. In October 2011, the DEA announced an emergency ban on MDPV, Methyone and Mephedrone, making testing for these substances more vital than ever.

#### **6-MONOACETYLMORPHINE (6-MAM)**

6-Monoacetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-MAM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day.

#### **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 is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.<sup>4</sup>

#### **OXYCODONE (OXY)**

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin<sup>®</sup> (controlled release), OxyIR<sup>®</sup>, OxyFast<sup>®</sup> (immediate release formulations), or Percodan<sup>®</sup> (aspirin) and Percocet<sup>®</sup> (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin<sup>®</sup>, has a longer duration of action (8-12 hours).

#### **PHENCYCLIDINE (PCP)**

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.<sup>5</sup> Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

#### **PROPOXYPHENE (PPX)**

Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

#### **SYNTHETIC MARIJUANA (K2)**

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.

Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclohexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", "K3" and others. These products may be smoked for their psychoactive effects.

#### **TRAMADOL (TRA)**

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptor. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.<sup>2</sup> Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both  $\Delta$  (d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucuronidation or sulfation in the liver.

#### **TRICYCLIC ANTIDEPRESSANTS (TCA)**

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

#### **ALCOHOL (ALC)**

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol use or intoxication. Screening is also an important deterrent against inappropriate alcohol consumption. The blood alcohol concentration at which a person becomes impaired is variable dependent on the individual. Parameters specific to the individual such as physical size, weight, activity level, eating habits and alcohol tolerance all affect the level of impairment. Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Alcohol Test is designed to detect ethyl alcohol in urine specimens.

#### **ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY**

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for Oxidants, Specific Gravity, pH, Creatinine, Nitrite and Glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

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

- **Oxidants (OX):** Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- **Specific Gravity (S.G.):** Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- **pH:** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in

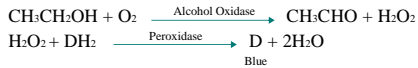
the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.

- **Nitrite (NIT):** Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- **Glutaraldehyde (GLU):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- **Creatinine (CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

#### PRINCIPLE

(1) The **One Step Multi-Drug Screen Cassette Test (Urine)** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in urine. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:



#### REAGENTS

Each test line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

#### ADULTERANT TESTS (SPECIMEN VALIDITY TEST) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.30%	99.70%
Specific Gravity (S.G.)	0.21%	99.79%
pH	0.06%	99.94%
Nitrite (NIT)	0.06%	99.94%
Glutaraldehyde (GLU)	0.02%	99.98%
Creatinine (CRE)	0.03%	99.97%

#### PRECAUTIONS

- For healthcare professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test dip card 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 dip card should be discarded according to local regulations.

#### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test dip card is stable through the expiration date printed on the sealed pouch. The test dip card must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.** Do not use beyond the expiration date.

#### SPECIMEN COLLECTION AND PREPARATION

##### Urine Assay

The urine specimen must 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 supernatant 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

1. 25 Sealed pouches each containing a test dip card and a desiccant
2. 1 Package insert
3. 2 Color Chart Cards for Adulterant Interpretation (when applicable)
4. 2 Color Chart Cards for Alcohol (when applicable)

##### Materials Required But Not Provided

- Timer

#### DIRECTIONS FOR USE

Allow the test dip card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

- 1) Remove the test dip card from the foil pouch.
- 2) Remove the cap from the test dip card. Label the dip card with patient or control identifications.
- 3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic dip card.
- 4) Replace the cap over the absorbent tip and lay the dip card flatly on a non-absorptive clean surface.
- 5) Read the adulteration strip at 2 minutes by comparing the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
- 6) Read the alcohol strip in 4 minutes by comparing the colors on the alcohol strip to the enclosed color chart.
- 7) Read the drug strip results at 5 minutes. **DO NOT INTERPRET RESULT AFTER 5 MINUTES.**



#### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

**Note:** There is no meaning attributed to line color intensity or width.

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

**IMPORTANT:** The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

##### What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by One Step Multi-Drug Screen Test Dip Card (Urine). The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

##### What Is A False Negative Test?

The definition of a false negative test is that the initial substance is present but isn't detected by One Step Multi-Drug Screen Test Dip Card (Urine). If the sample is diluted, or the sample is adulterated that may cause false negative result.

#### ALCOHOL/ADULTERANT INTERPRETATION

(Please refer to the color chart)

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

#### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate

membrane wicking and correct procedural technique.

#### LIMITATIONS

1. The One Step Multi-Drug Screen Cassette Test (Urine) 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.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
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. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the **One Step Multi-Drug Screen Cassette Test (Urine)**. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Specimen	AMP	AMP 500	AMP 300	BAR	BAR 200	BUP	BZO
Positive	91.7%	95.8%	96.7%	95.0%	94.2%	93.3%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	95.8%	97.9%	98.3%	97.5%	97.1%	96.7%	95.8%

Specimen	BZO 200	COC	COC 150	COT	EDDP	EDDP 100	ETG
Positive	92.5%	95.8%	95.0%	92.5%	94.2%	93.3%	95.0%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	96.3%	97.9%	97.5%	96.3%	97.1%	96.7%	97.5%

Specimen	ETG 300	FEN	FEN 200	FEN 100	FEN 20	K2	K2 25
Positive	95.8%	97.5%	95.8%	93.3%	97.5%	93.3%	95.8%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	98.8%	97.9%	96.7%	98.8%	96.7%	97.9%

Specimen	KET	KET 100	LSD	MET	MET 500	MET 300	MDMA
Positive	95.8%	91.7%	91.7%	95%	95.8%	95.8%	95.0%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	95.8%	95.8%	97.5%	97.9%	97.9%	97.5%

Specimen	MOP	MLQ	6-MAM	MTD	OPI	OXY	PCP
Positive	96.7%	91.7%	92.5%	95.0%	88.3%	93.3%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	98.3%	95.8%	96.3%	97.5%	94.2%	96.7%	95.8%

Specimen	PPX	THC	THC 25	THC 20	TCA	TRA	MDPV
Positive	95.0%	95.8%	94.2%	91.7%	95.0%	93.3%	94.2%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.5%	97.9%	97.1%	95.8%	97.5%	96.7%	97.1%

##### Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each dip card by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methylendioxypropylvalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines. The cut-off value for the dip card is verified.

##### Analytical Specificity

The following table lists compounds that are positively detected in urine by the **One Step Multi-Drug Screen Cassette Test (Urine)** at 5 minutes.



Drug	Concentration (ng/mL)
<b>AMPHETAMINE (AMP)</b>	
D-Amphetamine	1,000
D,L - Amphetamine (Amphetamine Sulfate)	1,000
Phentermine	1,250
(+/-)-4-Hydroxyamphetamine HCL	600
L-Amphetamine	20,000
3,4-Methylenedioxyamphetamine HCl (MDA)	1,500
d-Methamphetamine	>100,000 ng/mL
1-Methamphetamine	>100,000 ng/mL
ephedrine	>100,000 ng/mL
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000 ng/mL
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000 ng/mL
<b>AMPHETAMINE (AMP 500)</b>	
D-Amphetamine	500
D,L-Amphetamine	750
L-Amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine (MDA)	800
d-Methamphetamine	>100,000
1-Methamphetamine	>100,000
ephedrine	>100,000
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000
<b>AMPHETAMINE (AMP 300)</b>	
D-Amphetamine	300
D,L-Amphetamine	450
L-Amphetamine	9,000
Phentermine	450
(+/-)-Methylenedioxyamphetamine (MDA)	600
<b>BARBITURATES (BAR)</b>	
Secobarbital	300
Amobarbital	300
Alphenal	750
Aprobarbital	250
Butabarbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
<b>BARBITURATES (BAR 200)</b>	
Secobarbital	200
Amobarbital	200
Alphenal	500
Aprobarbital	200
Butabarbital	2,000
Butethal	2,000
Butalbital	2,000
Cyclopentobarbital	300
Pentobarbital	2,000
<b>BENZODIAZEPINES (BZO)</b>	
Alprazolam	200
Bromazepam	1,560
Chlordiazepoxide HCL	1,560
Clobazam	100

Drug	Concentration (ng/mL)
Clonazepam	780
Clorazepate Dipotassium	200
Delorazepam	1,560
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
a-Hydroxyalprazolam	1260
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Oxazepam	300
Temazepam	100
Triazolam	2,500
<b>BENZODIAZEPINES (BZO200)</b>	
Alprazolam	200
Bromazepam	1,000
Chlordiazepoxide HCL	1,000
Clobazam	80
Clonazepam	500
Clorazepate Dipotassium	100
Delorazepam	1,000
Desalkylflurazepam	300
Diazepam	100
Estazolam	2,000
Flunitrazepam	300
a-Hydroxyalprazolam	840
(±) Lorazepam	1,000
RS-Lorazepam glucuronide	100
Midazolam	10,000
Nitrazepam	100
Norchlordiazepoxide	100
Nordiazepam	300
Oxazepam	200
Temazepam	800
Triazolam	2,000
<b>BUPRENORPHINE (BUP)</b>	
Buprenorphine	10
Norbuprenorphine	20
<b>COCAINE (COC)</b>	
Benzoylcocaine	300
Cocaine ethylene	300
Cocaine HCl	300
<b>COCAINE (COC 150)</b>	
Benzoylcocaine	150
Cocaine ethylene	2,500
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000
<b>COTININE (COT)</b>	
Cotinine	200

Drug	Concentration (ng/mL)
Nicotine	6,250
<b>MDMA (ECSTASY)</b>	
D,L-3,4-Methylenedioxyamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
d-methamphetamine	2500
d-amphetamine	>100,000
l-amphetamine	>100,000
l-methamphetamine	>100,000
<b>ETHYL GLUCURONIDE (EtG 500)</b>	
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500
<b>ETHYL GLUCURONIDE (EtG 300)</b>	
Ethyl-β-D-glucuronide	300
Ethyl-β-D-glucuronide-D5	300
<b>FENTANYL (FEN)</b>	
Norfentanyl	20
Fentanyl	300
<b>FENTANYL (FEN20)</b>	
Norfentanyl	20
Fentanyl	300
<b>FENTANYL (FEN200)</b>	
Norfentanyl	15
Fentanyl	200
Sufentanyl	50,000
Fenfluramine	50,000
<b>FENTANYL (FEN 100)</b>	
Norfentanyl	10
Fentanyl	100
Buspirone	>100,000
Sufentanyl	25,000
Fenfluramine	25,000
<b>KETAMINE (KET)</b>	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4-hydroxyphenyl cyclohexyl piperidine	50,000
<b>KETAMINE (KET 100)</b>	
Ketamine	100
Norketamine	100
Methoxy-amphetamine	1,250
Promethazine	2,500
4-hydroxyphenyl cyclohexyl piperidine	5,000
<b>LYSERGIC ACID DIETHYLAMIDE (LSD)</b>	
D-lysergic acid diethylamide	20
Fentanyl	75
Norfentanyl	300

Drug	Concentration (ng/mL)
<b>MARIJUANA (THC)</b>	
Delta-9-Tetrahydrocannabinol	50,000
11-nor-delta-9-THC-carboxyglucuronide	75
(-)-11-nor-9-carboxy-delta9-THC	75
11-Nor-Δ <sup>9</sup> -Tetrahydrocannabinol	50
11-Hydroxy-Δ <sup>9</sup> -Tetrahydrocannabinol	5,000
11-Nor-Δ <sup>8</sup> -Tetrahydrocannabinol	50
Δ <sup>8</sup> -THC-COOH	50,000
<b>MARIJUANA (THC 25)</b>	
Delta-9-Tetrahydrocannabinol	25,000
11-nor-delta-9-THC-carboxyglucuronide	37.5
(-)-11-nor-9-carboxy-delta9-THC	37.5
11-Nor-Δ <sup>9</sup> -Tetrahydrocannabinol	25
11-Hydroxy-Δ <sup>9</sup> -Tetrahydrocannabinol	2,500
11-Nor-Δ <sup>8</sup> -Tetrahydrocannabinol	25
Δ <sup>8</sup> -THC-COOH	25,000
<b>MARIJUANA (THC 20)</b>	
Delta-9-Tetrahydrocannabinol	20,000
11-nor-delta-9-THC-carboxyglucuronide	30
(-)-11-nor-9-carboxy-delta9-THC	30
11-Nor-Δ <sup>9</sup> -Tetrahydrocannabinol	20
11-Hydroxy-Δ <sup>9</sup> -Tetrahydrocannabinol	2,000
11-Nor-Δ <sup>8</sup> -Tetrahydrocannabinol	20
Δ <sup>8</sup> -THC-COOH	20,000
<b>METHADONE (MTD)</b>	
Methadone	300
Doxylamine	5,000
<b>EDDP (Methadone Metabolites)</b>	
EDDP	300
Disopyramide	50,000
Methadone	>100,000
EMDP	500
<b>EDDP100 (Methadone Metabolites)</b>	
EDDP	100
Disopyramide	20,000
Methadone	>100,000
EMDP	200
<b>METHAMPHETAMINE (mAMP)</b>	
D-Methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
Methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxy-methamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
<b>METHAMPHETAMINE (MET 500)</b>	
p-Hydroxymethamphetamine	15,000
l-Methamphetamine	4,000


Drug	Concentration (ng/mL)
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	75,000
d-Methamphetamine	500
3,4-Methylenedioxy-methamphetamine (MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	50,000
Trimethobenzamide	20,000
Ranitidine (Zantac)	50,000
Fenfluramine	50,000
<b>METHAMPHETAMINE (MET 300)</b>	
p-Hydroxymethamphetamine	10,000
l-Methamphetamine	3,000
Mephentermine	15,000
d,l-Amphetamine	50,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	50,000
d-Methamphetamine	300
3,4-Methylenedioxy-methamphetamine (MDMA)	1,000
d-Amphetamine	30,000
Chloroquine	7,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	12,000
Procaine (Novocaine)	30,000
Trimethobenzamide	12,000
Ranitidine (Zantac)	30,000
Fenfluramine	30,000
<b>METHAQUALONE (MQL)</b>	
Methaqualone	300
<b>METHYLENEDIOXYPYROVALERONE (MDPV)</b>	
3,4-Methylenedioxy-pyrovalerone	1,000
Ethylone HCl	1,200
Methylone	50,000
Pyrovalerone	50,000
<b>6-MONOACETYLMORPHINE (6-MAM)</b>	
6-Moonacetylmorphine	10
Morphine	>500,000
Codeine	>600,000
Dextromethorphan	>100,000
Dihydrocodeine	>100,000
Heroin HCl	250
Hydrocodone	>100,000
Hydromorphone	>100,000
Imipramine	>100,000
Levorphanol	>10,000
NorMeperidine	>10,000
Normorphine	>100,000
Nalorphine	>100,000
Naloxone	>100,000
Naltrexone	>100,000
Norcodeine	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000

Drug	Concentration (ng/mL)
<b>MORPHINE (MOP)</b>	
Morphine	300
O6-Acetylmorphine	400
Codeine	300
EthylMorphine	100
Heroin	600
Hydromorphone	500
Hydrocodone	50,000
Levorphanol	1,500
Oxycodone	30,000
Procaine	15,000
Thebaine	6,240
<b>MORPHINE (OPI, MOP2000)</b>	
Morphine	2,000
O6-Acetylmorphine	2,500
Codeine	1,000
EthylMorphine	250
Heroin	5,000
Hydromorphone	2,500
Hydrocodone	5,000
Oxycodone	75,000
Thebaine	13,000
<b>OXYCODONE (OXY)</b>	
Naloxone hydrochloride	10,000
Naltrexone hydrochloride	50,000
Oxycodone	100
Hydrocodone	5,000
Hydromorphone	5,000
Oxymorphone-D3	5,000
Oxymorphone	200
N-Benzylisopropylamine	2,500
<b>PHENCYCLIDINE (PCP)</b>	
Phencyclidine	25
4-Hydroxy Phencyclidine	90
<b>PROPOXYPHENE (PPX)</b>	
Norpropoxyphene	300
d-Propoxyphene	300
<b>K2 (SYNTHETIC CANNABINOID)</b>	
JWH-018 5-Pentanoic acid metabolite	50
JWH-018 5-Hydroxypentyl metabolite	500
JWH-018 4-Hydroxypentyl metabolite	400
JWH-018 N-(4-hydroxypentyl) metabolite solution	5,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	5,000
JWH-073 4-butanoic acid metabolite	50
JWH-073 4-Hydroxybutyl metabolite	500
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000

Drug	Concentration (ng/mL)
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
<b>K2 (SYNTHETIC CANNABINOID) 25 ng/mL</b>	
JWH-018 5-Pentanoic acid metabolite	25
JWH-018 5-Hydroxypentyl metabolite	250
JWH-018 4-Hydroxypentyl metabolite	200
JWH-018 N-(4-hydroxypentyl) metabolite solution	2,500
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	2,500
JWH-073 4-butanoic acid metabolite	25
JWH-073 4-Hydroxybutyl metabolite	250
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
<b>TRAMADOL (TRA )</b>	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000
<b>Tricyclic Antidepressants (TCA)</b>	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	50,000
Desipramine	5,000
Doxepine	10,000
Imipramine	10,000
Maprotiline	100,000
Nordoxepin	10,000
Promazine	50,000
Promethazine	2,500
Trimipramine	50,000
Cyclobenzaprine Hydrochloride	5,000
Norclomipramine	50,000

#### Precision

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

 Zhejiang Orient Gene Biotech Co., Ltd  
Address: 3787#, East Yangguang Avenue, Dipu Street,  
Anji 313300, Huzhou, Zhejiang, China  
Tel: +86-572-5226111 Fax: +86-572-5226222  
Website: www.orientgene.com

**EC REP** Shanghai International Holding Corp. GmbH (Europe)  
Add: Eiffestrasse 80, 20537 Hamburg, Germany

**REF** GBDOA-1X5

Drug Conc. (Cut-off range)	AMP	AMP 500	AMP 300	BAR	BAR 200	BZO	BZO 200	BUP
	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	50 0	50 0	50 0	50 0	50 0	50 0	50 0	50 0
-75% Cut-off	50 0	50 0	50 0	50 0	50 0	50 0	50 0	50 0

-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	20	30	20	30	22	28	23	27	23	27	18	32	24	26	28	22
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	COC	COC150	COT	EDDP	EDDP 100	ETG	ETG 300	FEN
	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	41	9
Cut-off	20	30	24	26	20	30	21	29
+25% Cut-off	0	50	0	50	0	50	3	47
+50% Cut-off	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	FEN 200	FEN 100	FEN 20	K2	K2 25	KET	KET 100	MET	MET 500
	- +	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	50	0	50	0	50	0	50	0	50
-75% Cut-off	50	0	50	0	50	0	50	0	50
-50% Cut-off	50	0	50	0	50	0	50	0	50
-25% Cut-off	46	4	43	7	50	0	50	0	45
Cut-off	28	22	20	30	22	28	18	32	22
+25% Cut-off	5	45	2	48	0	50	0	50	6
+50% Cut-off	0	50	0	50	0	50	0	50	0
+75% Cut-off	0	50	0	50	0	50	0	50	0
+100% Cut-off	0	50	0	50	0	50	0	50	0

Drug Conc. (Cut-off range)	OXY	MET 300	MDMA	MOP	MQL	6-MAM	MTD	OPI
	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	48	50
Cut-off	24	26	25	24	26	22	28	24
+25% Cut-off	0	50	0	50	0	50	6	5
+50% Cut-off	0	50	0	50	0	50	0	0
+75% Cut-off	0	50	0	50	0	50	0	0
+100% Cut-off	0	50	0	50	0	50	0	0

Drug Conc. (Cut-off range)	PCP	PPX	THC	THC 25	THC 20	TCA	TRA	LSA	MDPV
	- +	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	50	0	50	0	50	0	50	0	50
-75% Cut-off	50	0	50	0	50	0	50	0	50
-50% Cut-off	50	0	50	0	50	0	50	0	50
-25% Cut-off	50	0	50	0	50	0	50	0	47
Cut-off	22	28	26	24	20	30	23	27	25
+25% Cut-off	0	50	0	50	0	50	0	50	1
+50% Cut-off	0	50	0	50	0	50	0	50	0
+75% Cut-off	0	50	0	50	0	50	0	50	0
+100% Cut-off	0	50	0	50	0	50	0	50	0

#### Effect of Urinary Specific Gravity

Twelve (12) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **One Step**

**Multi-Drug Screen Cassette Test (Urine)** was tested in duplicate using 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 aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **One Step Multi-Drug Screen Cassette Test (Urine)**. 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 Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2(Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methyleneoxypropyvalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Cassette Test (Urine)** at a concentration of 100 µg/mL.










#### Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Pseudoephedrine	Quinidine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinine
Acetylsalicylic acid	Dexamethasone	Labeltalol	Salicylic acid
Amiloride	Dextromethorphan	Loperamide	Serotonin
Amoxicillin	Desipramine	Meprobamate	Sulfamethazine
Ampicillin	Diflunisal	Methoxyphenamine	Sulindac
l-Ascorbic acid	Digoxin	Methylphenidate	Tetracycline
Apomorphine	Droperidol	Nalidixic acid	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-Acetate
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine Hydrochloride
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	α-Hydroxyhippuric acid	Perphenazine	D,L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol-(+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

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5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.

#### INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#

Revision Date: 2022-05-31  
B21769-03

# Fecal Occult Blood Rapid Test Cassette (Feces)



## INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in 1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

## INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibody-sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

## PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated with anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

## MATERIALS PROVIDED

- 20 Test cassettes
- 20 Specimen collection tubes with buffer
- 1 Package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Clock or timer

## STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. **Do not use specimen with visible blood for the testing.**
6. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air conditioning.

## PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
  - Bleeding hemorrhoids
  - Constipating bleeding
  - Urinary bleeding.
2. Dietary restrictions are not necessary.
  3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

## SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

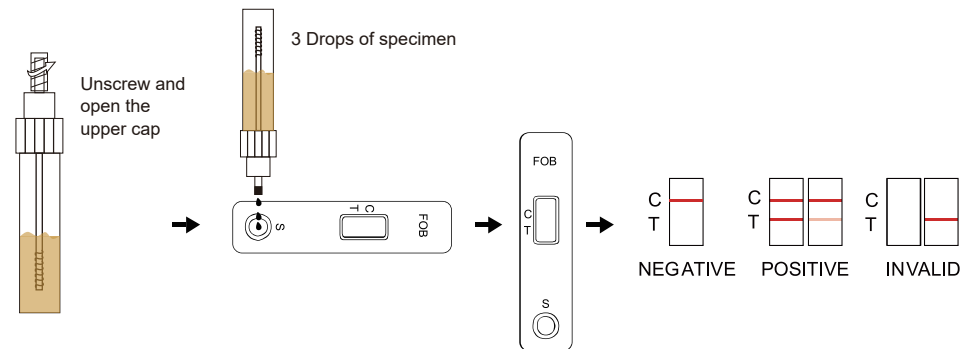
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

**Note:** Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

## TEST PROCEDURE

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

1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**Positive:** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

**Negative:** One colored line appears in the control line region (C). No line appears in the test line region (T).

**Invalid:** Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**NOTE:**

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

# Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids, or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid in diagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

## PERFORMANCE CHARACTERISTICS

### 1. Sensitivity: 99.6%

Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.

### 2. Prozone Effect:

It is observed that this FOB test can detect 2 mg/mL hemoglobin.

### 3. Specificity: 99.9%










Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standard concentration.


Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL


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 GEFOB-602b