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

Digitally signed by Dolgopol Iulian
Date: 2026.03.17 11:29:34 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

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

Report No.: SH2398804

Valid from: 2024-03-17
Valid until: 2027-03-16

Date, 2024-03-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

CE-DOC-OG038
Version 2.0

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)

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

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: August 11, 2020

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

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

CE-DOC-OG048
Version 3.0

CE

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)

D-Dimer Rapid Test Cassette (Whole Blood/Plasma)	GDDDI-402b

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: QARAD BV

EC Representative's Address: Cipalstraat 3, 2440 Geel BELGIUM

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 11, 2021

Joyce Pang

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

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

Joyce Pang

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

D-Dimer Rapid Test Cassette (Whole Blood/Plasma)

CE

INTENDED USE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of D-dimer in human whole blood or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT). Any reactive specimen with the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

During blood coagulation process, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerise to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Although fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, only degradation products from cross-linked fibrin contain D-dimer and are called cross-linked fibrin degradation products. Therefore, fibrin derivatives in human blood or plasma containing D-dimer are a specific marker of fibrinolysis.

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid test that qualitative detects the presence of D-dimer in whole blood or plasma specimens at the sensitivity of 500 ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of D-dimer in whole blood or plasma. At the level of claimed sensitivity, the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) shows no cross-reactivity interference from the related Troponin I, Troponin T, CK-MB, Myoglobin or others at high physiological levels.

PRINCIPLE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is immunochromatographic assay including D-Dimer specific monoclonal antibody conjugated to colloidal gold particles, second D-Dimer specific monoclonal antibody on test line and Goat anti-mouse IgG antibody on the control line. When the specimen containing D-Dimer is added to sample pad, it moves to conjugate pad and forms a complex (D-Dimer and antibody-gold conjugate). The complex migrates through a nitrocellulose membrane by capillary action and captured at test line which is second D-Dimer specific monoclonal antibody has been bound. The complex is concentrated at test line and a pink or purple line is showed if the D-Dimer concentration is higher than the clinically established cut-off. Uncaptured gold conjugate continues to flow towards control line which Goat anti-mouse IgG is bound and forms a pink or purple color line, indicating test is working as designed and the result is valid. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) containing Anti-D-dimer particles and Anti-D-dimer coated on the membrane.

MATERIALS SUPPLIED

25 Sealed pouches each containing a test cassette, a pipette dropper and a desiccant
1 Buffer, 4.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer Lancing device for whole blood test

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
3. This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
4. Read the entire procedure carefully prior to testing.
5. Do not eat, drink or smoke in any area where specimens and kits are handled.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
8. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

1. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is intended for use with human whole blood or plasma specimens only.
2. Only clear, non-hemolyzed specimens are recommended for use with this test. Whole blood or Plasma should be separated as soon as possible to avoid hemolysis.
3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
6. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
7. Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

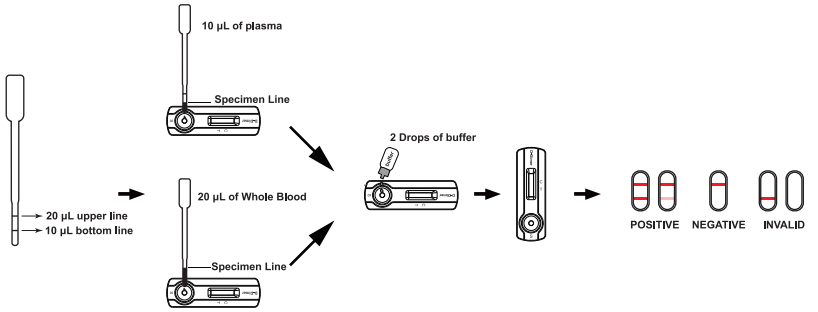
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

For Whole Blood Specimen: With the 10/20µL mini plastic dropper provided, draw the whole blood specimen to the upper scale line as showed in the following image and then transfer drawn whole blood into the sample well (S) of the test device., then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

For Plasma Specimen: With the 10/20µL mini plastic dropper provided, draw the plasma specimen to the bottom scale line as showed in the following image and then transfer drawn plasma into the sample well (S) of the test device. Then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 10 and 20µL of volume.

3. As the test begins to work, color will migrate across the membrane.
4. Wait for the colored band(s) to appear. The result should be read in 10 minutes. Do not interpret the result after 15 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. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of D-dimer in whole blood or plasma specimens only. Neither the quantitative value nor the rate of increase in D-dimer can be determined by this qualitative test.
2. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) will only indicate the qualitative level of D-dimer in the specimen and should not be used as the sole criteria for the diagnosis of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
3. During the process of serum is formed, also fibrinogen is converted to fibrin by the activation of thrombin and it also can be detected by D-dimer antibody. So serum specimen can't be used for D-Dimer Rapid Test Device (Whole Blood/Plasma).
4. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) cannot detect less than 500 ng/mL D-dimer in specimens. A negative result at any time does not preclude the possibility of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
5. False negative readings can occur if the sample is taken either too early after thrombus formation, if testing is delayed for several days or if the sample was take too later after the occurrence of thromboembolic infarction, because the D-dimer concentration may decrease to normal values after one week already. Additionally, a treatment with anti-coagulants prior sample collection can render the test negative because it prevents thrombus extension.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. E.g. use "Wells score" for DVT resp. PE, Ultrasound, quantitative laboratory D-Dimer results etc.
7. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been evaluated with a leading commercial D-dimer EIA test using clinical specimens. The results show that the sensitivity of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is 98.6% and the specificity is 98.6% relative to the leading EIA test.

Method		EIA		Total Results
D-Dimer Rapid Test Cassette	Results	Positive	Negative	
	Positive	71	3	74
	Negative	1	211	212
Total Results		72	214	286

Relative Sensitivity: 98.6%
Relative Specificity: 98.6%
Accuracy: 98.6%

2. Precision

Within-run precision has been determined by using 15 replicates of below five specimens: D-dimer specimen levels at 0 ng/mL, 500 ng/mL, 1,000 ng/mL, 1,500 ng/mL and 3,000 ng/mL. The specimens were correctly identified at the prescribed reading time.

3. Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: 0 ng/mL, 500 ng/mL, 1,000ng/mL, 1,500 ng/mL and 3,000 ng/mL of D-dimer. Three different lots of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) have been tested using these specimens. The specimens were correctly identified at the prescribed reading time.

4. Cross-reactivity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been tested with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis, anti-HIV, anti-H.pylori, IM heterophile antibodies, anti-CMV, anti-Rubella and anti-Toxoplasma positive specimens. The results showed no cross-reactivity.

5. Interfering Substances

The following potentially interfering substances were added to D-dimer negative and positive specimens, repectively.

Substances	Concentration
Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Albumin	10,500 mg/dL
Creatin	200 mg/dL
Hemoglobin	1,000 mg/dL
Bilirubin	1,000 mg/dL
Oxalic Acid	600 mg/dL
Cholesterol	800 mg/dL
Triglycerides	1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCE

1. Gaffney, P.J. D-dimer History of Discovery, Characterisation and Utility of this and other Fibrin Fragments. Fibrinolysis 7 Suppl 2:2-8; 1993
2. Lane, D.A. et al. Characterisation of Serum Fibrinogen and Fibrin Fragments Produced During Disseminated Intravascular Coagulation. Haematology. 40: 609-615; 1978.
3. Scarvelis, D and Wells, P.S. Diagnosis and Treatment of Deep Vein Thrombosis. Can. Med. Assoc. J. 175 (9):1087-92; 2006
4. Bick, R.L. et al. Diagnostic Efficacy of the D-dimer assay in Disseminated Intravascular Coagulation (DIC) Thromb. Res. 65:785-790; 1992.
5. Bick, R.L. et al. Disseminated Intravascular Coagulation: Objective Clinical and Laboratory Diagnosis, Treatment, and Assessment of Therapeutic Response. Semin. Thromb. Hemost. 22(1): 69-88; 1996.
6. Hunt, F.A. et al. Serum Cross-Linked Fibrin (XDP) and Fibrinogen/Fibrin Degradation Products (FDP) in Disorders Associated with Activation of the Coagulation or Fibrinolytic Systems. Br. J. Haematol. 60: 715-722; 1985.
7. Subramanian, R.M. et. al. Does an Immunochromatographic D-dimer exclude acute lower limb deep venous thrombosis? Emer. Med. Austral. 18: 457-463; 2006.
8. Runyon, M.S. et. al. Comparison of the Simplify D-dimer assay performed at the bedside with a laboratory based quantitative D-dimer assay for the diagnosis of pulmonary embolism in a low prevalence emergency department population. Emerg. Med. J. 25:70-75; 2008.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226 111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP QARAD BV
Cipalstraat 3, 2440 Geel BELGIUM

REF GDDDI-402b

Revision Date: 2022-10-08
B22211-02

One Step Multi-Drug Screen Test Cassette (Urine)
Package Insert

CE

Package insert for testing of any combination of the following drugs: Acetaminophen, Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Cotinine, Clonazepam, Ecstasy, Ethyl Glucuronide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, K2 Synthetic Cannabinoid, K3 (AB-Pinaca), Ketamine, Kratom, Lysergic acid diethylamide, Marijuana, EDDP, Methadone, Methamphetamine, Methaqualone, Methcathinone, Methylenedioxypyrovalerone, Methylphenidate, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Pregabalin, Propoxyphene, UR-144, Carisoprodol, Tramadol and Tricyclic Antidepressants.

A rapid, one step screening test for the simultaneous, qualitative detection of Acetaminophen, Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Cotinine, Clonazepam, Ecstasy, Ethyl Glucuronide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, K2 Synthetic Cannabinoid, K3 (AB-Pinaca), Ketamine, Kratom, Lysergic acid diethylamide, Marijuana, EDDP, Methadone, Methamphetamine, Methaqualone, Methcathinone, Methylenedioxypyrovalerone, Methylphenidate, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Pregabalin, Propoxyphene, UR-144, Carisoprodol, Tramadol, Tricyclic Antidepressants and the metabolites in human urine.

For 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 Test Cassette (Urine)** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Acetaminophen (ACE)	Acetaminophen	5,000
Amphetamine (AMP)	D-Amphetamine	1,000
Amphetamine (AMP)	D-Amphetamine	500
Amphetamine (AMP)	D-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Barbiturates (BAR)	Secobarbital	200
Buprenorphine (BUP)	Buprenorphine	10
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO)	Oxazepam	200
Cocaine (COC)	Benzoylecgonine	300
Cocaine (COC)	Benzoylecgonine	150
Cotinine (COT)	Cotinine	200
Clonazepam (CLO)	Clonazepam	500
MDMA (Ecstasy)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
MDMA (Ecstasy)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	300
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500
Fentanyl (FEN)	Fentanyl	300
Fentanyl (FEN)	Fentanyl	200
Fentanyl (FEN)	Norfentanyl	20
Fentanyl (FEN)	Norfentanyl	10
Gabapentin (GAB)	Gabapentin	1,000
Hydrocodone (HCD)	Hydrocodone	10
Hydromorphone (HMO)	Hydromorphone	300
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50
K2 Synthetic Cannabinoid	JWH-073/JWH-018	25
K3 (AB-Pinaca)	AB-Pinaca	10
Ketamine (KET)	Ketamine	1,000
Ketamine (KET)	Ketamine	100
Kratom (KRA)	Mitragynine	250
Lysergic acid diethylamide (LSD)	D-lysergic acid diethylamide	20
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	25
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
Methadone (MTD)	Methadone	300
Methadone (MTD)	Methadone	200
Methamphetamine (MET)	D-Methamphetamine	1,000
Methamphetamine (MET)	D-Methamphetamine	500
Methamphetamine (MET)	D-Methamphetamine	300
Methaqualone (MQL)	Methaqualone	300
Methcathinone (MTC)	Methcathinone	300
Methylenedioxypyrovalerone (MDPV)	3,4-Methylenedioxypyrovalerone	1,000
Methylphenidate (MPD)	Methylphenidate	300
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	20
Morphine (MOP 300)	Morphine	300
Morphine (OPI, MOP 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Pregabalin (PGB)	Pregabalin	1,000
Pregabalin (PGB)	Pregabalin	500
Propoxyphene (PPX)	Propoxyphene	300
UR-144	Synthetic Cannabinoid	50
Carisoprodol (SOMA)	Carisoprodol	1,000
Tramadol (TRA)	Tramadol	200
Tramadol (TRA)	Tramadol	100
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000

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

ACETAMINOPHEN (ACE)

Paracetamol, also known as Tylenol, Panadol and Bufferin, is a metabolite of fenacetin in vivo. It works by inhibiting prostaglandin synthase, a thermoregulatory center in the hypothalamus. Reduce the synthesis and release of prostaglandin PGE1, bradykinin and histamine. Main effect of PGE1 in nerve center, it will lead to reduce the central body temperature set-point, surface temperature sensors feel relatively, which caused by neuromodulation peripheral vascular expansion, sweating and antipyretic effect, its inhibition of prostaglandin synthesis of central nervous system function similar to aspirin, but weak anti-inflammatory effects. It has no effect on platelet and coagulation mechanism.

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.

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.

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.

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 Benzoylecgonine.[1,2] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[2]

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%.1 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.2 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.

CLONAZEPAM (CLO)

Clonazepam (CLZ), sold under the brand name Klonopin among others, is a medication used to prevent and treat seizures, panic disorder, and for the movement disorder known as akathisia. It is a tranquilizer of the benzodiazepine class. It is taken by mouth.[1] It begins having an effect within an hour and lasts between 6 and 12 hours.[2]

Common side effects include sleepiness, poor coordination, and agitation.[1] Long-term use may

result in tolerance, dependence, and withdrawal symptoms if stopped abruptly.[1] Dependence occurs in one-third of people who take clonazepam for longer than four weeks.[3] It may increase risk of suicide in people who are depressed.[1, 4] If used during pregnancy it may result in harm to the baby. It binds to GABAA receptors and increases the effect of the neurotransmitter gamma-Aminobutyric acid (GABA).[3]

As a major metabolite, 7-aminoclonazepam be used to monitor use of the parent drug, clonazepam. Clonazepam, marketed as Klonopin and Rivotril, is a long-acting benzodiazepine with anxiolytic, anticonvulsant, muscle relaxant, and hypnotic properties.

MDMA (ECSTASY)

Methylenedioxymethamphetamine (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 Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

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.

GABAPENTIN (GAB)

Gabapentin is an anti-epileptic drug, also called an anticonvulsant. It affects chemicals and nerves in the body that are involved in the cause of seizures and some types of pain. Gabapentin is used in adults to treat neuropathic pain (nerve pain) caused by herpes virus or shingles (herpes zoster). In epilepsy, it may be used for those with partial seizures. It is recommended as one of a number of first line medications for the treatment of neuropathic pain in diabetic neuropathy, postherpetic neuralgia, and central neuropathic pain. Common side effects include sleepiness and dizziness. Serious side effects may include an increased risk of suicide, aggressive behaviour, and drug reaction with eosinophilia and systemic symptoms.

HYDROCODONE (HCD)

Hydrocodone is used to treat moderate to severe pain, although it is often prescribed to treat mild pain as well. In liquid formulations, it is used as an antitussive to treat cough. In one study comparing the potency of hydrocodone to that of oxycodone, it was found that it took 50% more hydrocodone to achieve the same degree of miosis (pupillary contraction). The investigators interpreted this to mean that oxycodone is about 50% more potent than hydrocodone.

However, in a study of emergency department patients with fractures, it was found that an equal amount of either drug provided about the same degree of pain relief, indicating that there is little practical difference between them when used for that purpose. Some references state that the analgesic action of hydrocodone begins in 20–30 minutes and lasts about 4–8 hours. The manufacturer's information says onset of action is about 10–30 minutes and duration is about 4–6 hours. Recommended dosing interval is 4–6 hours.

HYDROMORPHONE (HMO)

Hydromorphone, also known as dihydromorphinone, is a centrally acting pain medication of the opioid class. It is made from morphine. It works by changing the way the brain and nervous system respond to pain. Hydromorphone extended-release tablets are used to relieve severe pain in people who are expected to need pain medication around the clock for a long time and who cannot be treated with other medications. Hydromorphone extended-release tablets should only be used to treat people who are tolerant (used to the effects of the medication) to opioid medications because they have taken this type of medication for at least one week and should not be used to treat mild or moderate pain, short-term pain, pain after an operation or medical or dental procedure, or pain that can be controlled by medication that is taken as needed.

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 cannabicyclo hexanol 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.

K3 (AB-PINACA)

AB-Pinaca is a compound that was first identified as a component of synthetic cannabis products in Japan in 2012. AB-Pinaca acts as a potent agonist for the CB1 receptor (Ki = 2.87 nM, EC50 = 1.2 nM) and CB2 receptor (Ki = 0.88 nM, EC50 = 2.5 nM) and fully substitutes for Δ9-THC in rat discrimination studies, while being 1.5x more potent.5 There have been a number of reported cases of deaths and hospitalizations in relation to this synthetic cannabinoid.

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.

KRATOM (KRA)

Kratom leaves produce narcotic-like effects when smoked, chewed, or drank as a suspension, which have recently attracted significant attention due to increased use in Western cultures as an alternative medicine. It is used in therapy for opiate addiction and chronic pain management. The addiction potential and adverse health consequences are becoming an important issue for health authorities. Extensive use of kratom results in prolonged sleep. The withdrawal symptoms include hostility, aggression, muscle pain and inability to work.

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 (Δ^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-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

2-Ethylidine-1.5-dimethyl-3.3-diphenylpyrrolidine (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.

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.

METHAMPHETAMINE (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulaDtion 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.

METHCATHINONE (MTC)

Methcathitone, commonly known as the zombie drug, is an amphetamine-like substance. It comes in powder form or a liquid mixed with water, and has a stimulant effect similar to that of amphetamines. Studies have shown that methcathitone can cause acute health problems and drug dependence.

"Zombie medicine" is known abroad as "bath salts". Cathinones are considered synthetic drugs, a relative of crystal meth. In the United States, there have been a number of cases of drug addicts eating their faces, which are believed to be "bath salts", hence the name "zombie drugs".

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 a ‘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, Methylone, 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 stimulants.

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, Methylone and Mephedrone, making testing for these substances more vital than ever.

METHYLPHENIDATE (MPD)

Methylphenidate (MPD) is a psychostimulant drug approved for treatment of ADHD or attention-deficit hyperactivity disorder, postural orthostatic tachycardia syndrome and narcolepsy. Methylphenidate primarily acts as a norepinephrine-dopamine reuptake inhibitor. Methylphenidate is most active at modulating levels of dopamine and to a lesser extent norepinephrine. Similar to cocaine, methylphenidate binds to and blocks dopamine transporters and norepinephrine transporters. Methylphenidate has both dopamine transporter and norepinephrine transporter binding affinity, with the dextro methylphenidate enantiomers displaying a prominent affinity for the norepinephrine transporter. Methylphenidate may also exert a neuroprotective action against the neurotoxic effects of Parkinson's disease and methamphetamine abuse. Methylphenidate taken orally has a bioavailability of 11-52% with a duration of action around 1-4 hours for instant release, 3–8 hours for sustained release, and 8–12 hours for extended release (Concerta). The half-life of methylphenidate is 2-3 hours, depending on the individual. The peak plasma time is achieved at about 2 hours

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.[4]

OXYCODONE (OXY)

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] 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® (controlled release), OxyIR®, OxyFast® (immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, 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.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

PREGABALIN (PGB)

Pregabalin is an anti-epileptic drug, also called an anticonvulsant. It affects chemicals and nerves in the body that are involved in the cause of seizures and some types of pain. Pregabalin is used in adults to treat neuropathic pain (nerve pain) caused by herpes virus or shingles (herpes zoster). In epilepsy, it may be used for those with partial seizures. It is recommended as one of a number of first line medications for the treatment of neuropathic pain in diabetic neuropathy, postherpetic neuralgia, and central neuropathic pain. Common side effects include sleepiness and dizziness. Serious side effects may include an increased risk of suicide, aggressive behaviour, and drug reaction with eosinophilia and systemic symptoms.

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.

UR-144

UR-144 is a new generation of synthetic cannabinoid, chemically different from the first generation. UR-144 is formed by substituting a naphthalene ring in JWH-018 with a tetrachmethyl cyclopropyl group. Most patients experience difficulty breathing and a rapid heart rate, while other side effects in users include vomiting, delusions, confusion, irritability and dilated pupils.

CARISOPRODOL (SOMA)

Carisoprodol is also known as Muscle Tranquility, Callitis, RELA. A derivative of methylalanine ester, it also has sedative and anti-anxiety effects and is used in the treatment of acute muscle spasms and sprains. Avoid dangerous mechanical operation during medication.

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.

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 receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2] Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ (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, glucoronidation or sulfation in the liver.

PRINCIPLE

The **One Step Multi-Drug Screen Test Cassette (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.

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.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test cassette 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 cassette 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 cassette is stable through the expiration date printed on the sealed pouch. The tst cassette 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 cassette, a dropper and a desiccant
2. 1 Package insert

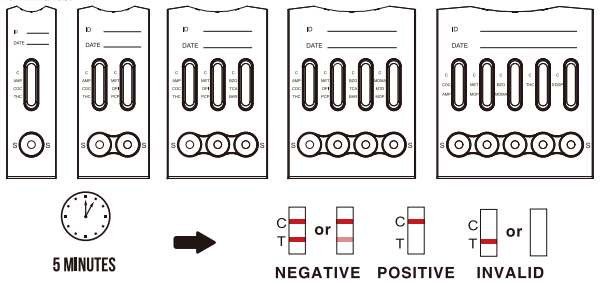
Materials Required but Not Provided

• Timer • Specimen collection container

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL total volume) to each specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret results after 10 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 Cassette (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 Methamphetamine is present but isn't detected by One Step Multi-Drug Screen Test Cassette (Urine). If the sample is diluted, or the sample is adulterated that may cause false negative result.

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 Test Cassette (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 Test Cassette (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	ACE	AMP	AMP 500	AMP 300	BAR	BAR 200	BUP
Positive	94.8%	93.3%	95.8%	96.7%	93.3%	94.2%	94.2%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.4%	96.7%	97.9%	98.3%	96.7%	97.1%	97.1%

Specimen	BZO	BZO 200	COC	COC 150	COT	CLO	MDMA
Positive	95.0%	93.3%	92.5%	97.5%	93.3%	95.6%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.5%	96.7%	96.3%	98.8%	96.7%	97.8%	95.8%

Specimen	MDMA 2,000	ETG	ETG 300	FEN	FEN 200	FEN 20	FEN 10
Positive	94.2%	95.0%	95.8%	95.0%	93.3%	92.5%	93.3%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.1%	97.5%	97.9%	97.5%	96.7%	96.3%	96.7%

Specimen	GAB	HCD	HMO	K2	K2 25	K3	KET
Positive	91.7%	96.3%	95.8%	93.3%	95.8%	95.0%	95.8%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	95.8%	98.2%	97.9%	96.7%	97.9%	97.5%	97.9%

Specimen	KET 100	KRA	LSD	THC	THC 25	EDDP	EDDP 100
Positive	91.7%	94.2%	93.3%	94.2%	94.2%	95%	93.3%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	95.8%	97.1%	96.7%	97.1%	97.1%	97.5%	96.7%

Specimen	MTD	MTD 200	MET	MET 500	MET 300	MQL	MTC
Positive	94.2%	95.4%	96.7%	96.7%	95.8%	91.7%	96.3%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.1%	97.7%	98.3%	98.3%	97.9%	95.8%	98.2%

Specimen	MDPV	MPD	6-MAM	6-MAM 20	MOP	OPI	OXY
Positive	95.8%	96.6%	93.3%	94.5%	97.5%	92.5%	93.3%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	98.3%	96.7%	97.3%	98.8%	96.3%	96.7%

Specimen	PCP	PGB	PGB 500	PPX	UR-144	SOMA	TRA
Positive	92.5%	94.2%	96.2%	95.0%	93.6%	94.6%	93.3%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	96.3%	97.1%	98.1%	97.5%	96.8%	97.3%	96.7%

Specimen	TRA 200	TCA
Positive	94.9%	92.5%
Negative	100%	100%
Total	97.5%	96.3%

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 device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Acetaminophen, Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Cotinine, Clonazepam, Ecstasy, Ethyl Glucuronide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, K2 Synthetic Cannabinoid, K3 (AB-Pinaca), Ketamine, Kratom, Lysergic acid diethylamide, Marijuana, EDDP, Methadone, Methamphetamine, Methaqualone, Methcathinone, Methylenedioxypyrovalerone, Methylphenidate, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Pregabalin, Propoxyphene, UR-144, Carisoprodol, Tramadol and Tricyclic Antidepressants. The cut-off value for the device is verified.

Analytical Specificity

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

Drug	Concentration (ng/mL)
ACETAMINOPHEN (ACE)	
Acetaminophen	5,000
AMPHETAMINE (AMP)	
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 HCI (MDA)	1,500
d-Methamphetamine	>100,000 ng/mL
l-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
AMPHETAMINE (AMP 500)	
D-Amphetamine	500
D,L-Amphetamine	750
L-Amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine (MDA)	800
d-Methamphetamine	>100,000
l-Methamphetamine	>100,000
ephedrine	>100,000
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000
AMPHETAMINE (AMP 300)	
D-Amphetamine	300
D,L-Amphetamine	450
L-Amphetamine	9,000
Phentermine	450
(+/-)-Methylenedioxyamphetamine (MDA)	600
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	750
Aprobarbital	250
Butabarbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
BARBITURATES (BAR 200)	
Secobarbital	200
Amobarbital	200
Alphenal	500
Aprobarbital	200
Butabarbital	2,000
Butethal	2,000
Butalbital	2,000
Cyclopentobarbital	300
Pentobarbital	2,000
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
BENZODIAZEPINES (BZO)	
Alprazolam	200
Bromazepam	1,560
Chlordiazepoxide HCL	1,560
Clobazam	100
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
BENZODIAZEPINES (BZO 200)	
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
COCAINE (COC)	
Benzoylecogonine	300
Cocaethylene	300
Cocaine HCl	300
COCAINE (COC 150)	
Benzoylecogonine	150
Cocaethylene	2,500
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000
COTININE (COT)	
Cotinine	200
Nicotine	6,250
CLONAZEPAM (CLO)	
7-Aminoclonazepam	500
ECSTASY (MDMA)	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300
d-methamphetamine	2500
d-amphetamine	>100,000
l-amphetamine	>100,000
l-methamphetamine	>100,000
ECSTASY (MDMA 2,000)	
3,4-Methylenedioxyamphetamine HCl (MDA)	12,000
3,4-Methylenedioxyethylamphetamine (MDEA)	1,200
L-Methamphetamine	50,000
(±)-MDMA	8,000
D-Methamphetamine	>400,000
D-Amphetamine	>400,000

L-Amphetamine	>400,000
ETHYL GLUCURONIDE (EtG 500)	
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500
ETHYL GLUCURONIDE (EtG 300)	
Ethyl-β-D-glucuronide	300
Ethyl-β-D-glucuronide-D5	300
FENTANYL (FEN)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN 200)	
Norfentanyl	15
Fentanyl	200
Sufentanyl	50,000
Fenfluramine	50,000
FENTANYL (FEN 20)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN 10)	
Norfentanyl	10
Fentanyl	150
GABAPENTIN (GAB)	
Gabapentin	1,000
Pregabalin	40,000
Ibupyofen	4,500
Triazolam	30,000
Bilirubin	50,000
Diflunisal	10,000
HYDROCODONE (HCD)	
Dihydrocodeine HCL	312.5
EthylMorphine	10,000
Hydrocodone	10
Hydromorphone	2,500
Levorphanol	10,000
Oxymorphone-D3	10,000
Codeine	2,500
Heroin Hydromorphone	>100,000
Oxymorphone	>100,000
6-acetylmorphine	>100,000
Nalorphine	>100,000
Norcodeine	50,000
Morphine	100,000
HYDROMORPHONE (HMO)	
Hydromorphone	300
Ranitidine	50,000
Gatifloxacin	6,250
Procaine	25,000
Morphine	12,500
Coteine Phosphate	12,500
Heroin	3,125
Naloxone hydrochloride	80,000

Naltrexone hydrochloride	781
Dihydrocodeine HCL	1,526
Hydrocodone	195
Levorphanol	50,000
Oxymorphone-D3	97.65
Codeine	6,250
Heroin Hydromorphone	6,250
Oxymorphone	24.4
6-acetylmorphine	50,000
LAAM HCl	50,000
K2 (SYNTHETIC CANNABINOID)	
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
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
K2 (SYNTHETIC CANNABINOID) 25 ng/mL	
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
K3 (AB-PINACA)	
AB-PINACA 5-hydroxypentyl	10
AB-PINACA 4-Hydroxypentyl metabolite	10
AB-PINACA	10
AB-FUPINACA	100
KETAMINE (KET)	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4-hydroxyphenyl cyclohexyl piperidine	50,000

KETAMINE (KET100)	
Ketamine	100
Norketamine	100
Methoxy-amphetamine	1,250
Promethazine	2,500
4-hydroxyphenyl cyclohexyl piperidine	5,000
KRATOM (KRA)	
Mitragynine	250
Mitragynine Metabolite	250
7-Hydroxymitragynine	600
Bilirubin	100,000
11-Hydroxy-Δ^9-Tetrahydrocannabinol	80,000
LYSERGIC ACID DIETHYLAMIDE (LSD)	
D-lysergic acid diethylamide	20
Fentanyl	75
Norfentanyl	300
MARIJUANA (THC)	
Delta-9-Tetrahydrocannabinol	50,000
11-nor-delta-9-THC-carboxyglucuronide	75
(-)-11-nor-9-carboxy-delta9-THC	75
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000
11-Nor-Δ^8-Tetrahydrocannabinol	50
Δ^8-THC-COOH	50,000
MARIJUANA (THC 25)	
Delta-9-Tetrahydrocannabinol	25,000
11-nor-delta-9-THC-carboxyglucuronide	37.5
(-)-11-nor-9-carboxy-delta9-THC	37.5
11-Nor-Δ^9-Tetrahydrocannabinol	25
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,500
11-Nor-Δ^8-Tetrahydrocannabinol	25
Δ^8-THC-COOH	25,000
METHADONE METABOLITES (EDDP)	
EDDP	300
Disopyramide	50,000
Methadone	>100,000
EMDP	500
METHADONE METABOLITES (EDDP 100)	
EDDP	100
Disopyramide	20,000
Methadone	>100,000
EMDP	200
METHADONE (MTD)	
Methadone	300
Doxylamine	5,000
METHADONE (MTD 200)	
(±)-Methadone	200
Doxylamine	>65,000
EDDP perchlorate	>65,000
EMDP	>65,000
LAAM HCl	>65,000

Alpha Methadol	>65,000
METHAMPHETAMINE (MET)	
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-Methylenedioxymethamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
METHAMPHETAMINE (MET 500)	
p-Hydroxymethamphetamine	15,000
l-Methamphetamine	4,000
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	75,000
d-Methamphetamine	500
3,4-Methylenedioxymethamphetamine (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
METHAMPHETAMINE (MET 300)	
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-Methylenedioxymethamphetamine (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
METHAQUALONE (MQL)	
Methaqualone	300
METHCATHINONE (MTC)	
Methcathinone	300
Ranitidine	50,000
Procaine hydrochloride	2,000
4-Methylethcathinone hydrochloride	1,000
Butylone HCl	100
Ethylone	1,000
R(+)-Methcathinone	10,000

S(-)-Methcathinone	300
(±)-MDMA	12,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Trimethobenzamide Hydrochloride	50,000
Cocaine HCl	>100,000
p-Hydroxymethamphetamine	65,000
D,L-Methamphetamine	15,000
Methylone hydrochloride	80
Mephedrone	20
Methedrone	20
Clonidine	50,000
Tetrahydrozoline	30,000
S(+)-Methamphetamine	4,000
METHYLENEDIOXYPYROVALERONE (MDPV)	
3,4-Methylenedioxypyrovalerone	1,000
Ethylone HCl	1,200
Methylone	50,000
Pyrovalerone	50,000
METHYLPHENIDATE (MPD)	
Methylphenidate	300
6-MONOACETYLMORPHINE (6-MAM)	
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
6-MONOACETYLMORPHINE (6-MAM 20)	
6-Moonacetylmorphine	20
Morphine	>1000,000
Codeine	>1200,000
Dextromethorphan	>200,000
Dihydrocodeine	>200,000
Heroin HCl	500
Hydrocodone	>200,000
Hydromorphone	>200,000
Imipramine	>200,000
Levorphanol	>20,000
NorMeperidine	>20,000
Normorphine	>200,000
Nalorphine	>200,000
Naloxone	>200,000
Naltrexone	>200,000
Norcodeine	>200,000

Oxycodone	>200,000
Oxymorphone	>200,000
MORPHINE (MOP)	
Morphine	300
O6-Acetylmorphine	400
Codeine	300
EthylMorphine	100
Heroin	600
Hydromorphone	5,000
Hydrocodone	10,000
Levorphanol	1,500
Oxycodone	30,000
Procaine	15,000
Thebaine	6,240
MORPHINE (OPI, MOP2000)	
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
OXYCODONE (OXY)	
Naloxone hydrochloride	10,000
Naltrexone hydrochloride	50,000
Oxycodone	100
Hydrocodone	5,000
Hydromorphone	25,000
Oxymorphone-D3	5,000
Oxymorphone	200
N-Benzylisopropylamine	2,500
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy Phencyclidine	90
PREGABALIN (PGB)	
Pregabalin (PGB)	1,000
PREGABALIN (PGB 500)	
Pregabalin (PGB)	500
PROPOXYPHENE (PPX)	
Norpropoxyphene	300
d-Propoxyphene	300
UR-144	
UR-144 5-Pentanoic	50
UR-144 4-Hydr oxypentyl metabolite	1,000
UR-144 5-Hydroxypentyl metabolite-D5 (indole-D5)	500
UR-144 5-Pentanoic acid metabolite	50
UR-144 5-Hydroxypentyl metabolite	500
UR-144 5-Pentanoic acid metabolite-D5 (indole-D5)	50
CARISOPRODOL (SOMA)	
Carisoprodol	1000
TRAMADOL (TRA)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000
TRAMADOL (TRA 100)	
Tramadol	100
N-desmethyl-tramadol	250
O-desmethyl-tramadol	10,000
TRICYCLIC ANTIDEPRESSANTS (TCA)	
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:

Drug Conc. (Cut-off range)	ACE		AMP		AMP 500		AMP 300		BAR		BAR 200		BUP		BZO	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	24	26	18	32	32	18	22	28	27	23	23	27	26	24	20	30
+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)	BZO 200		COC		COC150		COT		CLO		MDMA		MDMA 2,000		ETG	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	44	6
Cut-off	24	26	18	32	31	19	20	30	29	21	30	20	24	26	23	27
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	8	42
+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)	ETG 300		FEN		FEN 200		FEN 20		FEN 10		GAB		HCD		HMO	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	42	8	50	0	46	4	50	0	49	1	48	2	50	0	50	0
Cut-off	23	27	22	28	22	28	22	28	25	25	22	28	24	26	23	27
+25% Cut-off	4	46	0	50	3	47	0	50	2	48	5	45	1	49	5	45
+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)	K2		K2 25		K3		KET		KET 100		KRA		LSD		THC	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	48	2	45	5	44	6	45	5	43	7	50	0
Cut-off	18	32	22	28	23	27	18	32	30	20	22	28	21	29	14	36
+25% Cut-off	0	50	0	50	3	47	6	44	3	47	4	46	3	47	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)	THC 25		EDDP		EDDP 100		MTD		MTD 200		MET		MET 500		MET 300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	41	9	50	0	50	0	50	0	50	0	50	0
Cut-off	23	27	21	29	30	20	28	22	27	23	22	28	28	22	25	25
+25% Cut-off	0	50	0	50	3	47	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)	MQL		MTC		MDPV		MPD		6-MAM		6-MAM20		MOP		OPI	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	48	2	44	6	47	3	49	1	50	0	50	0	50	0	50	0
Cut-off	24	26	26	24	23	27	25	25	23	27	24	26	20	30	20	30
+25% Cut-off	6	44	5	45	4	46	2	48	5	45	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)	OXY		PCP		PGB		PGB 500		PPX		UR-144		SOMA		TRA	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	45	5
Cut-off	16	34	16	34	24	26	23	27	25	25	26	24	23	27	28	22
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	1	49
+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)	TRA 100		TCA	
	-	+	-	+
0% Cut-off	50	0	50	0
-75% Cut-off	50	0	50	0

-50% Cut-off	50	0	50	0
-25% Cut-off	50	0	50	0
Cut-off	23	27	22	28
+25% Cut-off	0	50	0	50
+50% Cut-off	0	50	0	50
+75% Cut-off	0	50	0	50
+100% Cut-off	0	50	0	50

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 Test Cassette (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 Test Cassette (Urine)**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Interference Compounds

A study was conducted to determine the interference compounds of the test with compounds in either drug-free urine or Acetaminophen, Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Cotinine, Clonazepam, Ecstasy, Ethyl Glucuronide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, K2 Synthetic Cannabinoid, K3 (AB-Pinaca), Ketamine, Kratom, Lysergic acid diethylamide, Marijuana, EDDP, Methadone, Methamphetamine, Methaqualone, Methcathinone, Methylenedioxypyrovalerone, Methylphenidate, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Pregabalin, Propoxyphene, UR-144, Carisoprodol, Tramadol and Tricyclic Antidepressants positive urine. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Test Cassette (Urine)** at a concentration of 100 µg/mL.

Non-interfering Compounds Tables

Acetophenetidin	Cortisone	Pseudoephedrine	Quinidine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinine
Acetylsalicylic acid	Dexamethasone	Labetalol	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, 3-Acetate
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Theobromine
Atropine	Ethopropazine	Niacinamide	Tolazamide
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrozoline
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Thiamine
Bilirubin	Fenoprofen	Noscapine	Thioridazine Hydrochloride
Beclomethasone	Furosemide	Octopamine	D/L-Tyrosine
Caffeine	Gentisic acid	Oxalic acid	Tolbutamide
Cannabidiol	Hemoglobin	Oxyphenbutazone	Triamterene
Carbamazepine	Hydralazine	Oxymetazoline	Trifluoperazine
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trimethoprim
Chlorothiazide	Hydrocortisone	Paclitaxel	D,L-Tryptophan
Chlorpheniramine	α-Hydroxyhippuric acid	Perphenazine	Uric acid
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Verapamil
Cholesterol	Isoproterenol-(+/-)	Prednisone	Zomepirac
Clonidine	Isoxsuprine	Prilocaine	

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3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.

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	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C~30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

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

Revision Date：2023-12-6
B23162-01

Troponin I

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. For professional in vitro diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.[1] Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.[2] After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.[3] cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.[4] Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.[5]

PRINCIPLE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
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. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
7. Humidity and temperature can adversely affect results.

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 off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

Materials Provided

1. Test cassettes 2.Disposable Droppers 3. Package insert

Materials Required But Not Provided

1. Specimen collection containers 2.Centrifuge (for plasma only)
3. Clock or Timer

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. Transfer **2-3 drops of serum or plasma** to the specimen well(S) of the device with a disposable pipette provided in the kit, and then start the timer.

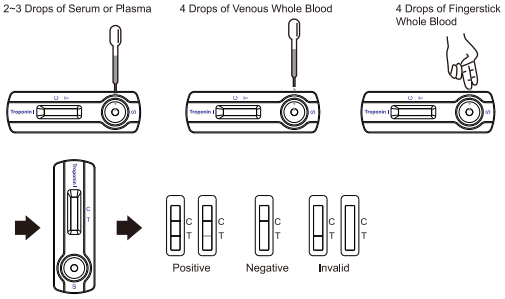
OR

Transfer **4 drops of whole blood** specimen to the specimen well(S) of the device with a disposable pipette provided in the kit, and then start the timer.

OR

Allow **4 hanging drops of fingerstick whole blood** specimen to fall into the center of the specimen well (S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.As the test begins to work, you will see color move across the membrane.

2. Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE:Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID:Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.

Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE: Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. 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. The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
2. The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

Method		Troponin I Rapid Test Cassette		Total Results
		Positive	Negative	
EIA	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

Relative Sensitivity: 98.6% (94.9%-99.8%)* Relative Specificity: 99.7% (98.3%-99.9%)*

Overall Agreement: 99.3% (98.1%-99.9%)* *95% Confidence Interval

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