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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Manufacturer:

ACON Laboratories, Inc.

5850 Oberlin Drive, #340
San Diego CA 92121
USA

**Product Category(ies): Blood glucose measuring systems for self testing
and self-testing devices for clinical chemistry,
hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1 104507 0003 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:V1_104507_0003_Rev.06)

Report no.:

SH22743EXT01

Valid from:

2022-05-04

Valid until:

2025-05-26

Date,

2022-05-04

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream,
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281),
On Call Sure Blood Glucose Monitoring System (OGM-211),
On Call Sure Sync Blood Glucose Monitoring System (OGM-212),
On Call Sure Blood Glucose Test Strips (OGS-211),
GIMA Blood Glucose Monitoring System,
GIMA Bluetooth Blood Glucose Monitoring System,
GIMA Blood Glucose Test Strips,
On Call GU Dual Blood Glucose & Uric Acid Monitoring



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

System (OGM-201),
On Call Blood Uric Acid Test Strips (OGS-201),
LH Ovulation Rapid Test Cassette (Urine),
Ovulation Rapid Test Midstream,
Ovulation & Pregnancy Test Combo Pack,
On Call Extra Voice Blood Glucose Monitoring System
(OGM-291),
Early Detection Pregnancy Test,
Digital Pregnancy Test,
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-161),
Go-Keto Blood Ketone Test Strips (OGS-161),
Go-Keto Blood Glucose Test Strips,
On Call Extra GM Blood Glucose Monitoring System(OGM-191),
On Call Extra GM Blood Glucose Test Strips (OGS-191),
On Call Plus GM Blood Glucose Monitoring System,
On Call Plus GM Blood Glucose Test Strips,
Go-Keto Urinalysis Reagent Strips

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana
B.C. CP, MEXICO

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121 USA

**We, the manufacturer, declare under our sole responsibility that the
in vitro diagnostic device:**

Device Name	REF Number
On Call® Plus Blood Glucose Monitoring System	G113-111
On Call® Plus Blood Glucose Meter	G113-211, G113-214
On Call® Plus Blood Glucose Test Strips	G133-111, G133-112, G133-114, G133-115, G133-117, G133-118, G133-119, G133-211
On Call® Plus Glucose Control Solution	G123-311

**classified for *Annex II List B* of the directive 98/79/EC,
meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it**

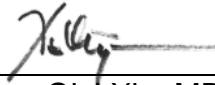
**The declaration according to Annex IV of the Directive
is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission**

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 06
Expiration Date: 2025-05-26

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany



Signed this 25 day of May, 2022
in San Diego, CA USA



Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.



5850 Oberlin Drive #340-San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Letter of Declaration

To whom it may concern:

We **Acon Laboratories, Inc.**, who is the legal manufacturer of Blood Glucose Monitoring System (Including Glucose Meter, Glucose test strip, Control Solution, Lancet and lancing device etc, to test the glucose level of human blood), have registered office at 10125 Mesa Rim Road, San Diego, CA 92121 USA, here to declare that:

- **On Call® Plus Strips** correspond with **On Call® Plus** Blood Glucose Monitoring System.
- We currently have in stock the tender required quantity of Meters, Strips and Lancets (1000/50000/50000).

This clarification letter will only be used for product registration, tender submission, sales and marketing of **On Call® Plus** Blood Glucose Monitoring System in **Moldova** it should not be used for any other business or non-business purposes.

Sincerely yours,

Eddie Shi

International Sales & Marketing Sales Manager
Diabetes Care

Acon Laboratories, Inc.





Certificate

No. Q5 104507 0001 Rev. 03

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

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 104507 0001 Rev. 03

Report No.: SH22743A01

Valid from: 2022-09-15
Valid until: 2025-09-06

Date, 2022-09-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 104507 0001 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

Address holder for registration only

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

Storage of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Design and Development of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644
Tijuana B.C. CP, MEXICO

Manufacture of
blood glucose test strips, antigen rapid test and IgG/IgM antibody
rapid test for infectious disease.

STATEMENT

We, ACON Laboratories, Inc., having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* authorize SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*

to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: January 3, 2023

Signature:



Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com

Specification

Feature	Specification
Technology	Biosensor/Electrochemical, Glucose oxidase (GOD)
Result Calibration	Plasma-equivalent
Test Time	10 seconds
Sample Size	0.5 µL
Sample Type	Fresh capillary whole blood
Hematocrit Range	25 - 60%
Glucose Test Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Memory Storage	300 results with date and time
Test Averaging	7, 14, 30-day averages
Data Transfer	USB
Control Solution	3 levels
Audio Feature	Optional beep for sample detection, error messages
Automatic Shutoff	2 minutes after last action
Battery	One (1) CR 2032 3.0V coin cell battery
Battery Life	1,000 measurements
Operating Conditions	41 - 113 °F (5 - 45°C) and 10 - 90% relative humidity
Strip Storage Temperature	2-35°C
Expiration Date	24 months (6 months after first opening)

Catalog

Product Name	Catalog No.	Contents			
On-Call® Plus Blood Glucose Monitoring System	G113-111 v †	1 Meter 1 Manual 10 Lancets	10 Test Strips 1 Carrying Case 1 Code Chip	1 Control Solution 1 1 Quick Reference Guide 1 Clear Cap (for testing on forearm and palm)	1 Lancing Device 1 Warranty Card
On-Call® Plus Blood Glucose Meter	G113-211 v †	1 Meter 1 Manual	1 Control Solution 1 1 Warranty Card	1 Carrying Case 1 Quick Reference Guide	
	G113-214 v	1 Meter 1 Manual 10 Lancets	1 Lancing Device 1 Carrying Case 1 Warranty Card	1 Control Solution 1 1 Quick Reference Guide 1 Clear Cap (for testing on forearm and palm)	
On-Call® Plus Blood Glucose Test Strips	G133-111 v †	50 Test Strips (25/vial)	1 Code Chip	1 Package Insert	
		50 Test Strips (50/vial)	1 Code Chip	1 Package Insert	
	G133-112 v	100 Test Strips (25/vial)	1 Code Chip	1 Package Insert	
	G133-114 v	10 Test Strips (10/vial)	1 Code Chip	1 Package Insert	
	G133-115 v	25 Test Strips (Individually Foil Wrapped)	1 Code Chip	1 Package Insert	
	G133-117 v	50 Test Strips (Individually Foil Wrapped)	1 Code Chip	1 Package Insert	
	G133-118 v	25 Test Strips (25/vial)	1 Code Chip	1 Package Insert	
On-Call® Plus Blood Glucose Test Strips and Lancets	G133-211 v	50 Test Strips (25/vial)	50 Lancets (25/bag)	1 Code Chip	1 Package Insert
On-Call® Plus Blood Glucose Control Solution	G123-311 v†	1 Control Solution 0	1 Control Solution 1	1 Control Solution 2	1 Package Insert
On-Call® Lancets	G124-10A v†	100 Lancets (25/bag)			
On-Call® Lancing Device	G124-11AV	1 Lancing Device		1 Package Insert	
On-Call® Diabetes Management Software Kit	G124-13A†	1 USB Data Transfer Cable		1 Installation Disk	

v CE Marked for sale in the European Community  0123 † US 510(k) Cleared and CLIA Waived



ACON Laboratories, Inc., 10125 Mesa Rim Road, San Diego, CA 92121, USA • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: info@aconlabs.com

Please visit our website for details: www.acondiabetescare.com

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1150944001

On-Call® Plus

Blood Glucose Monitoring System

Delivers Value and Quality

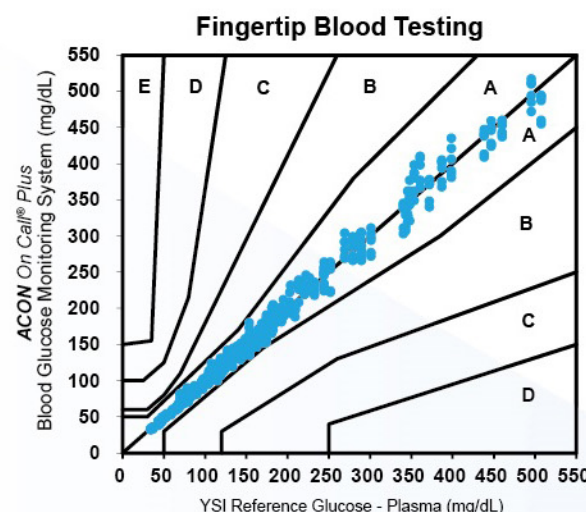
- 0.5 µL Blood Sample
- Accurate & Reliable Results
- 25 - 60% HCT Range
- US 510(k) & CE

ACON®
Diabetes Care

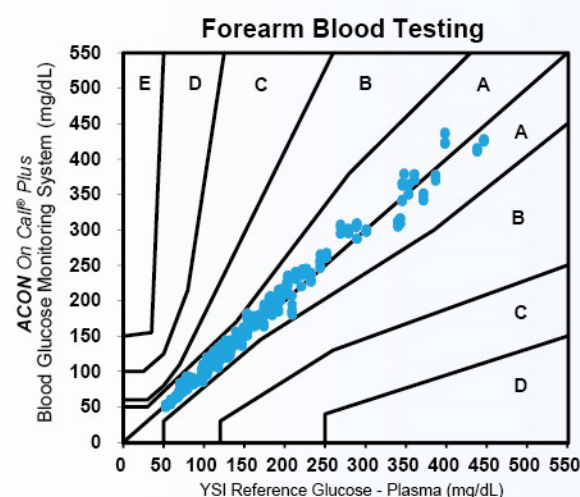


Accurate and Reliable

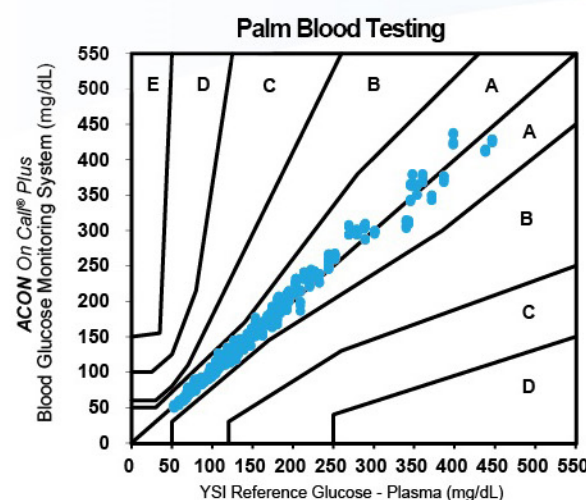
Extensive clinical studies proved the accuracy of *On-Call[®] Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



Consensus Error Grid Analysis Clinical Trial - Fingertip Capillary Blood, by Technican ACON On Call® Plus Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
290 / 462 (62.8%)	432 / 462 (93.5%)	462 / 462 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
145 / 198 (73.2%)	193 / 198 (97.5%)	198 / 198 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
658 / 660 (99.7%)		



Consensus Error Grid Analysis Clinical Trial - Forearm Capillary Blood, by Technician ACON On Call® Plus Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ± 5%	Within ± 10%	Within ± 15%
202 / 444 (45.5%)	375 / 444 (84.5%)	440 / 444 (99.1%)
System Accuracy Results for Glucose Concentration <100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
110 / 168 (65.5%)	154 / 168 (91.7%)	168 / 168 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
608 / 612 (99.3%)		



Consensus Error Grid Analysis Clinical Trial - Palm Capillary Blood, by Technican ACON On Call® Plus Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
219 / 444 (49.3%)	395 / 444 (89.0%)	441 / 444 (99.3%)
System Accuracy Results for Glucose Concentration < 100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
130 / 168 (77.4%)	166 / 168 (98.8%)	168 / 168 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
609 / 612 (99.5%)		

Key Features



Authority Certificate



CE certificate



USFDA CFG certificate



Health Canada certificate



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



CE-DOC-OG060
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

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

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

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

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

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

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

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

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-OG318
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 Drugs of Abuse Test Strip (Urine)	GBXXX-101
One Step Drugs of Abuse Test Cassette (Urine)	GBXXX-102
One Step Drugs of Abuse Test Dip Card (Urine)	GBXXX-105

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: CMC Medical Devices & Drugs S.L

EC Representative's Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

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: April 4, 2022

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



Certificate

No. Q5 092305 0001 Rev. 01

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. 01

Report No.: SH2198802

Valid from: 2022-04-11

Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

See Scope of Certificate



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

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 Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21



Handwritten signature in blue ink.

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China
电话 Tel:+86-572-5226111 传真 Fax: +86-572-5226222 邮编 P.C.:313300

Fecal Occult Blood Rapid Test Cassette (Feces)



INTENDED USE

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

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

INTRODUCTION

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

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

PRINCIPLE

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

MATERIALS PROVIDED

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

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

STORAGE AND STABILITY

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

PRECAUTIONS

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

PATIENT PREPARATION

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

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

SPECIMEN COLLECTION AND PREPARATION

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

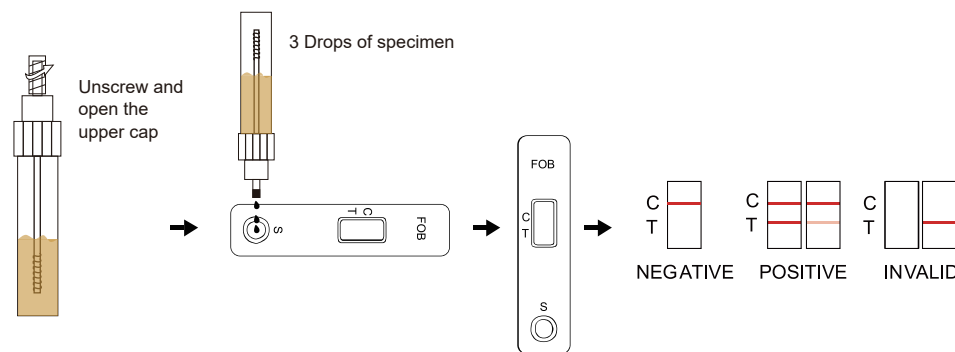
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside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

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

TEST PROCEDURE

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

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



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

NOTE:

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

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.

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

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

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

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%

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

2. Prozone Effect:

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

3. Specificity: 99.9%

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

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

REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, Vol. 1985;88:820.
2. Blebea J. and Ncpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

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

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

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

GEFOB-602b

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

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

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

For forensic 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 Dip Card (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs, drug metabolites and alcohol at the following cut-off concentrations in urine:		
Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Amphetamine (AMP)	D-Amphetamine	500
Amphetamine (AMP)	D-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Barbiturates (BAR)	Secobarbital	200
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO)	Oxazepam	200
Benzodiazepines (BZO)	Oxazepam	150
Buprenorphine (BUP)	Buprenorphine	10
Buprenorphine (BUP)	Buprenorphine	5
Cocaine (COC)	Benzoylcegonine	300
Cocaine (COC)	Benzoylcegonine	150
Cocaine (COC)	Benzoylcegonine	100
Cotinine (COT)	Cotinine	200
MDMA (Ecstasy)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
MDMA (Ecstasy)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	300
MDMA (Ecstasy)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	150
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	300
Fentanyl (FEN)	Fentanyl	300
Fentanyl (FEN)	Fentanyl	200
Fentanyl (FEN)	Fentanyl	100
Fentanyl (FEN)	Norfentanyl	50
Fentanyl (FEN)	Norfentanyl	20
Fentanyl (FEN)	Norfentanyl	10
Gabapentin (GAB)	Gabapentin	1,000
Gabapentin (GAB)	Gabapentin	2,000
Hydrocodone (HCD)	Hydrocodone	10
Hydromorphone (HMO)	Hydromorphone	300
Ketamine (KET)	Ketamine	1,000

Ketamine (KET)	Ketamine	100
Kratom (KRA)	Mitragynine	250
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50
K2 Synthetic Cannabinoid	JWH-073/JWH-018	25
K3 (AB-Pinaca)	AB-Pinaca	10
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	40
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	25
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	20
Methadone (MTD)	Methadone	300
Methadone (MTD)	Methadone	200
Methadone (MTD)	Methadone	50
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrr olidine (EDDP)	300
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrr olidine (EDDP)	100
Methamphetamine (MET, mAMP)	D-Methamphetamine	1,000
Methamphetamine (MET, mAMP)	D-Methamphetamine	500
Methamphetamine (MET, mAMP)	D-Methamphetamine	300
Methaqualone (MQL)	Methaqualone	300
Methylenedioxypyrovalerone (MDPV)	3,4-Methylenedioxypyrovalerone	1000
Methylphenidate (MPD)	Methylphenidate	300
6-MonoacetylMorphine (6-MAM)	6-MonoacetylMorphine	10
Opiates (MOP 300)	Morphine	300
Opiates (MOP 100)	Morphine	100
Opiates (OPI, MOP2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Oxycodone (OXY)	Oxycodone	300
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Tramadol (TRA)	Tramadol	200
Tramadol (TRA)	Tramadol	100
Alcohol (ALC).	Ethanol	>0.04% B.A.C

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

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

AMPHETAMINE (AMP)

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

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets.

The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

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

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

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, and a Buprenorphine/Naloxone combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

COCAINE (COC)

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

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

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

ETHYL GLUCURONIDE (ETG)

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

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

FENTANYL (FEN)

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

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.

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 addition 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.

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 (K_i = 2.87 nM, EC₅₀ = 1.2 nM) and CB₂ receptor (K_i = 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.

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

METHADONE (MTD)

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

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.

METHAMPHETAMINE (MET, mAMP)

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

METHAQUALONE (MQL)

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in European countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

METHYLENEDIOXYPPYRVALERONE (MDPV)

Bath salts’, a form of designer drugs, also promoted as ‘plant food’ or ‘research chemicals’, is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised as ‘legal’ highs. The technical term for ‘bath salts’ is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of ‘bath salts’. In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinone, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada.

Established as one of the main ingredients for ‘bath salts’, among other synthetic stimulants like Mephedrone, Methylene, 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 uses 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, Methylene 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 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.

OPIATES (OPI)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the 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, dihydrohydroxycodone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (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%).

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.

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, glucuronidation or sulfation in the liver.

ALCOHOL (ALC)

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at

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

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

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

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

- **Oxidants (OX):** Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- **Specific Gravity (S.G.):** Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- **pH:** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.
- **Nitrite (NIT):** Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- **Glutaraldehyde (GLU):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- **Creatinine (CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

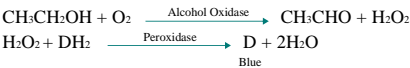
PRINCIPLE

(1) The **One Step Multi-Drug Screen Test Dip Card (Urine)** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

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

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



REAGENTS

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

ADULTERANT TESTS(SPECIMEN VALIDITY TEST) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.30%	99.70%
Specific Gravity (S.G.)	0.21%	99.79%

pH	0.06%	99.94%
Nitrite (NIT)	0.06%	99.94%
Glutaraldehyde (GLU)	0.02%	99.98%
Creatinine (CRE)	0.03%	99.97%

PRECAUTIONS

- *For forensic use only.*
- Do not use after the expiration date.
- The Test Dip Card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used Test Dip Card should be discarded according to local regulations.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time is 2-7 hours, so you may collect urine samples 2-7 hours after suspected drug use.

HOW TO COLLECT URINE?

1. Urinate directly into the provided urine cup.
2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.
3. The residual urine sample in the urine cup is for your self-testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Test dip card
- Package insert
- Color chart card for adulterant interpretation (when applicable)
- Color chart card for alcohol (when applicable)

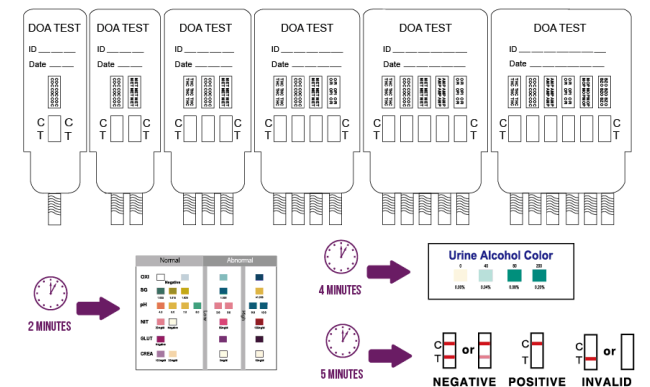
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

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

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



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

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

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

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

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

What Is A False Positive Test?

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

What Is A False Negative Test?

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

ALCOHOL/ADULTERANT INTERPRETATION

(Please refer to the color chart)

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

QUALITY CONTROL

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

LIMITATIONS

- The One Step Multi-Drug Screen Test Dip Card (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.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.

- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- 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.
- The test does not distinguish between drugs of abuse and certain medications.
- 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 Dip Card (Urine)**. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Specimen	AMP	AMP500	AMP300	BAR	BAR200	BZO	BZO200	BZO150
Positive	91.7%	95.8%	96.7%	95.0%	94.2%	91.7%	92.5%	92.6%
Negative	100%	100%	100%	100%	100%	100%	100%	100.0%
Total	95.8%	97.9%	98.3%	97.5%	97.1%	95.8%	96.3%	96.3%

Specimen	BUP	BUP 5	COC	COC150	COC100	COT	MDMA150	MDMA500
Positive	93.3%	92.8%	95.8%	95.0%	95.2%	92.5%	99.1%	97.3%
Negative	100%	100%	100%	100%	100%	100%	100.0%	100.0%
Total	96.7%	96.4%	97.9%	97.5%	97.6%	96.3%	99.6%	98.7%

Specimen	MDMA	ETG	ETG300	FEN	FEN200	FEN100	FEN50	FEN20
Positive	95.0%	98.7%	94.9%	97.5%	95.8%	93.3%	94.6%	97.5%
Negative	100%	100.0%	100.0%	100%	100%	100%	100.0%	100%
Total	97.5%	99.4%	97.5%	98.8%	97.9%	96.7%	97.3%	98.8%

Specimen	FEN10	GAB	GAB2000	HCD	HMO	KET	KET100	KRA
Positive	93.3%	91.7%	>99%	91.7%	95.8%	95.8%	91.7%	94.2%
Negative	100%	100%	>99%	100%	100%	100%	100%	100%
Total	96.7%	95.8%	>99%	95.8%	97.9%	97.9%	95.8%	97.1%

Specimen	K2	K2 25	K3	LSL	THC	THC40	THC25	THC20
Positive	93.3%	95.8%	>99%	91.7%	95.8%	95.1%	94.2%	91.7%
Negative	100%	100%	>99%	100%	100%	100%	100%	100%
Total	96.7%	97.9%	>99%	95.8%	97.9%	97.6%	97.1%	95.8%

Specimen	MTD	MTD200	MTD50	EDDP	EDDP100	MET	MET500	MET300
Positive	95.0%	94.2%	95.6%	94.2%	93.3%	95%	95.8%	95.8%
Negative	100%	100%	100.0%	100%	100%	100%	100%	100%
Total	97.5%	97.1%	97.8%	97.1%	96.7%	97.5%	97.9%	97.9%

Specimen	MQL	MDPV	MPD	6-MAM	MOP	MOP100	OPI	OXY
Positive	91.7%	94.2%	98.4%	92.5%	96.7%	95.1%	88.3%	93.3%
Negative	100%	100%	100%	100%	100%	100%	100%	100%
Total	95.8%	97.1%	99.2%	96.3%	98.3%	97.6%	94.2%	96.7%

Specimen	OXY300	PCP	PPX	TCA	TRA	TRA100
Positive	94.1%	91.7%	95.0%	95.0%	93.3%	95.7%
Negative	100%	100%	100%	100%	100%	100.0%
Total	97.1%	95.8%	97.5%	97.5%	96.7%	97.9%

Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each dip card by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, Ketamine, Kratom, K2 (Synthetic Cannabinoid), K3 (AB-Pinaca), Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Methamphetamine, Methaqualone, Methylenedioxypropylvalerone, Methylphenidate, 6-Monoacetylmorphine, Opiates, Oxycodone, Phenylethylamine, Propoxyphene, Tricyclic Antidepressants and Tramadol. The cut-off value for the dip card is verified.

Analytical Specificity

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

Drug	Concentration (ng/ml)
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 HCl (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 (AMP500)	
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 (AMP300)	
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
Butobarbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
BARBITURATES (BAR200)	
Secobarbital	200
Amobarbital	200
Alphenal	500
Aprobarbital	200
Butobarbital	2,000
Butethal	2,000
Butalbital	2,000
Cyclopentobarbital	300
Pentobarbital	2,000
BENZODIAZEPINES (BZO)	
Alprazolam	200

Drug	Concentration (ng/ml)
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 (BZO200)	
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
BENZODIAZEPINES (BZO150)	
Alprazolam	150
Bromazepam	750
Chlordiazepoxide HCL	750
Clobazam	60
Clonazepam	375
Clorazepate Dipotassium	75
Delorazepam	750
Desalkylflurazepam	225
Diazepam	75
Estazolam	1,500
Flunitrazepam	225
a-Hydroxyalprazolam	630
(±) Lorazepam	750
RS-Lorazepam glucuronide	75

Drug	Concentration (ng/ml)
Midazolam	7,500
Nitrazepam	75
Norchlordiazepoxide	75
Nordiazepam	225
Oxazepam	150
Temazepam	600
Triazolam	1,500
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
BUPRENORPHINE (BUP5)	
Buprenorphine	5
Norbuprenorphine	10
COCAINE (COC)	
Benzoyllecgonine	300
Cocaethylene	300
CocaineHCl	300
COCAINE (COC150)	
Benzoyllecgonine	150
Cocaethylene	2,500
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000
COCAINE (COC100)	
Benzoyllecgonine	100
Cocaethylene	1,667
Cocaine	334
Ecgonine	8,334
Ecgonine methylester	33,334
COTININE (COT)	
Cotinine	200
Nicotine	6,250
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(MDMA300)	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	300
3,4-Methylenedioxyamphetamine HCl (MDA)	1,800
3,4-Methylenedioxyethyla-amphetamine (MDEA)	180
d-methamphetamine	1,500
d-amphetamine	>100,000
l-amphetamine	>100,000
l-methamphetamine	>100,000
ECSTASY(MDMA150)	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	150

Drug	Concentration (ng/ml)
3,4-Methylenedioxyamphetamine HCl (MDA)	900
3,4-Methylenedioxyethyla-amphetamine (MDEA)	90
d-methamphetamine	750
d-amphetamine	>100,000
l-amphetamine	>100,000
l-methamphetamine	>100,000
ETHYL GLUCURONIDE (EtG500)	
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500
ETHYL GLUCURONIDE (EtG300)	
Ethyl-β-D-glucuronide	300
Ethyl-β-D-glucuronide-D5	300
FENTANYL (FEN)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN50)	
Norfentanyl	50
Fentanyl	1,000
NORFENTANYL (FEN20)	
Norfentanyl	20
Fentanyl	300
NORFENTANYL (FEN10)	
Norfentanyl	10
Fentanyl	150
FENTANYL (FEN200)	
Norfentanyl	15
Fentanyl	200
Sufentanyl	50,000
Fenfluramine	50,000
FENTANYL (FEN100)	
Norfentanyl	10
Fentanyl	100
Buspirone	>100,000
Sufentanyl	25,000
Fenfluramine	25,000
GABAPENTIN (GAB)	
Gabapentin	1,000
Pregabalin	40,000
Ibuprofen	4,500
Triazolam	30,000
Bilirubin	50,000
Diflunisal	10,000
GABAPENTIN (GAB2000)	
Gabapentin	2,000
Pregabalin	50,000
Ibuprofen	10,000
Triazolam	90,000
Bilirubin	90,000
Diflunisal	15,000

Drug	Concentration (ng/ml)
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
Coteline 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
KETAMINE (KET)	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4-hydroxyphenyl cyclohexyl piperidine	50,000
KETAMINE (KET)	
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-Δ9-Tetrahydrocannabinol	80,000
K2 (SYNTHETIC CANNABINOID)	
JWH-018 5-Pentanoic acid metabolite	50

Drug	Concentration (ng/ml)
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) 25ng/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 (K3)	10
AB-FUBINACA metabolite	10,000
AB-PINACA 5-Hydroxypentyl metabolite	3
AB-PINACA 4-Hydroxypentyl metabolite	3
UR-144 S-Hydropentyl metabolite	50,000
UR-144 5-Pentanoic Acid metabolite	5000
UR-144 4-Hydroxypentyl metabolite	40,000
AB-PINACA 5-Pentanoic acid metabolite	2
XLR-11	70,000
APINACA (AKB-48) 5-Hydroxypentyl metabolite	25,000
Melatonin	500,000
MAB-CHMINACA	2,250
AB-CHMINACA	750
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

Drug	Concentration (ng/ml)
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	5,000
11-Nor-Δ ⁸ -Tetrahydrocannabinol	50
Δ ⁸ -THC-COOH	50,000
MARIJUANA (THC40)	
Delta-9-Tetrahydrocannabinol	40,000
11-nor-delta-9-THC-carboxyglucuronide	60
(-)-11-nor-9-carboxy-delta9-THC	60
11-Nor-Δ ⁹ -Tetrahydrocannabinol	40
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	4,000
11-Nor-Δ ⁸ -Tetrahydrocannabinol	40
Δ ⁸ -THC-COOH	40,000
MARIJUANA (THC25)	
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
MARIJUANA (THC20)	
Delta-9-Tetrahydrocannabinol	20,000
11-nor-delta-9-THC-carboxyglucuronide	30
(-)-11-nor-9-carboxy-delta9-THC	30
11-Nor-Δ ⁹ -Tetrahydrocannabinol	20
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	2,000
11-Nor-Δ ⁸ -Tetrahydrocannabinol	20
Δ ⁸ -THC-COOH	20,000
METHADONE (MTD)	
Methadone	300
Doxylamine	5,000
METHADONE (MTD200)	
Methadone	200
PCP (Phencyclidine)	140,000
Diphenhydramine HCl	200,000
Doxylamine	40,000
EDDP perchlorate	100,000
Disopyramide	30,000
METHADONE (MTD 50)	
Methadone	50
PCP (Phencyclidine)	35,000
Diphenhydramine HCl	50,000
Doxylamine	10,000
EDDP perchlorate	25,000
Disopyramide	7,500
EDDP (Methadone Metabolites)	
EDDP	300
Disopyramide	50,000
Methadone	>100,000
EMDP	500
EDDP100 (Methadone Metabolites)	
EDDP	100

Drug	Concentration (ng/ml)
Disopyramide	20,000
Methadone	>100,000
EMDP	200
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
Methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxy-methamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
METHAMPHETAMINE (MET500)	
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-Methylenedioxy-methamphetamine (MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	50,000
Trimethobenzamide	20,000
Ranitidine (Zantac)	50,000
Fenfluramine	50,000
METHAMPHETAMINE (MET300)	
p-Hydroxymethamphetamine	10,000
l-Methamphetamine	3,000
Mephentermine	15,000
d,l-Amphetamine	50,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	50,000
d-Methamphetamine	300
3,4-Methylenedioxy-methamphetamine (MDMA)	1,000
d-Amphetamine	30,000
Chloroquine	7,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	12,000
Procaine (Novocaine)	30,000
Trimethobenzamide	12,000
Ranitidine (Zantac)	30,000
Fenfluramine	30,000
METHAQUALONE (MQL)	
Methaqualone	300
METHYLENEDIOXYPYROVALERONE (MDPV)	
3,4-Methylenedioxy-pyrovallorone	1,000
Ethylone HCl	1,200
Methylone	50,000
Pyrovalerone	50,000

Drug	Concentration (ng/ml)
METHYLPHENIDATE (MPD)	
Methylphenidate	300
6-MONOACETYLMORPHINE (6-MAM)	
6-Moonacetyl-morphine	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
OPIATES (MOP)	
Morphine	300
O6-Acetylmorphine	400
Codeine	300
EthylMorphine	100
Heroin	600
Hydromorphone	500
Hydrocodone	50,000
Levorphanol	1,500
Oxycodone	30,000
Procaine	15,000
Thebaine	6,240
OPIATES (MOP100)	
Morphine	100
O6-Acetylmorphine	130
Codeine	100
EthylMorphine	30
Heroin	200
Hydromorphone	160
Hydrocodone	16,000
Levorphanol	500
Oxycodone	10,000
Procaine	5,000
Thebaine	2,080
OPIATES (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

Drug	Concentration (ng/ml)
Thebaine	13,000
OXYCODONE (OXY)	
Naloxone hydrochloride	10,000
Naltrexone hydrochloride	50,000
Oxycodone	100
Hydrocodone	5,000
Hydromorphone	5,000
Oxymorphone-D3	5,000
Oxymorphone	200
N-Benzylisopropylamine	2,500
OXYCODONE (OXY300)	
Naloxone hydrochloride	30,000
Naltrexone hydrochloride	>100,000
Oxycodone	300
Hydrocodone	15,000
Hydromorphone	15,000
Oxymorphone-D3	15,000
Oxymorphone	600
N-Benzylisopropylamine	7,500
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy Phencyclidine	90
PROPOXYPHENE (PPX)	
Norpropoxyphene	300
d-Propoxyphene	300
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
TRAMADOL (TRA)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000
TRAMADOL (TRA100)	
Tramadol	100
N-desmethyl-tramadol	250
O-desmethyl-tramadol	10,000

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)	AMP		AMP500		AMP300		BAR		BAR200		BZO		BZO200		BZO150	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	22	28	20	30	22	28	23	27	23	27	18	32	24	26	29	21
+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)	BUP		BUP5		COC		COC150		COC100		COT		MDMA		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	28	22	22	28	20	30	24	26	24	26	20	30	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)	ETG300		FEN		FEN200		FEN100		FEN20		FEN50		FEN10		GAB	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	43	7	50	0	50	0	50	0	48	2
Cut-off	23	27	22	28	28	22	20	30	22	28	23	27	25	25	22	28
+25% Cut-off	4	46	0	50	5	45	2	48	0	50	0	50	0	50	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)	GAB2000		HCD		HMO		KET		KET100		KRA		K2		K2 25	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	45	5	44	6	45	5	50	0	50	0
Cut-off	29	21	22	28	23	27	18	32	30	20	22	28	18	32	22	28
+25% Cut-off	1	49	0	50	5	45	6	44	3	47	4	46	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)	K3		LSD		THC		THC40		THC25		THC20		MTD		MTD200	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	23	27	21	29	20	30	20	30	23	27	25	25	28	22	28	22
+25% Cut-off	3	47	5	45	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)	MTD 50		EDDP		EDDP100		MET		MET500		MET300		MQL		MDPV	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	50	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	50	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	48	50	48	2
Cut-off	28	22	21	29	30	20	24	26	25	25	25	25	24	22	24	26
+25% Cut-off	0	50	0	50	3	47	0	50	0	50	0	50	6	0	7	43
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	0	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	0	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	0	0	50

Drug Conc. (Cut-off range)	MPD		6-MAM		MOP		MOP100		OPI		OXY		OXY300		PCP	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	23	27	22	27	22	28	24	26	22	28	24	26	26	24	22	28
+25% Cut-off	0	50	5	45	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)	PPX		TCA		MDMA150		MDMA300		TRA		TRA100	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	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% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	47	3	50	0
Cut-off	26	24	22	28	25	25	23	27	25	25	22	28
+25% Cut-off	0	50	0	50	0	50	0	50	1	49	0	50
+50% Cut-off	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
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Fifteen (15) 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 Dip Card (Urine)** was tested in duplicate using ten 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 Dip Card (Urine)**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

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

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Pseudoephedrine	Quinidine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinine
Acetylsalicylic acid	Dexamethasone	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,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-Acetate

Toxicology Urine Test



Product Description	Format	Cut-off Value	Qualification
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
Amphetamine (AMP) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Barbiturates (BAR) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/200 ng/mL	CE 510(k)
Benzodiazepines (BZO) Test	Strip/Cassette/Dip Card/Cup	600/400/300/200/100 ng/mL	CE 510(k)
Buprenorphine (BUP) Test	Strip/Cassette/Dip Card/Cup	10/5 ng/mL	CE 510(k)
Caffeine (CAF) Test	Strip/Cassette/Dip Card/Cup	6000 ng/mL	/
Carisoprodol (SOMA) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	CE
Clonazepam (CLO) Test	Strip/Cassette/Dip Card/Cup	500/100 ng/mL	CE
Cocaine (COC) Test	Strip/Cassette/Dip Card/Cup	600/300/150/100 ng/mL	CE 510(k)
Codeine (COD) Test	Strip/Cassette/Dip Card/Cup	2000 ng/mL	CE
Cotinine (COT) Test	Strip/Cassette/Dip Card/Cup	400/300/200/100/50 ng/mL	CE
Ecstasy (MDMA) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250/150 ng/mL	CE 510(k)
Ethyl Glucuronide (EtG) Test	Strip/Cassette/Dip Card/Cup	500/300ng/mL	CE
Fentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	300/200/100/50 ng/mL	CE
Norfentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCD) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
Ketamine (KET) Test	Strip/Cassette/Dip Card/Cup	3000/2000/1000/500/100 ng/mL	CE
Kratom (KRA) Test	Strip/Cassette/Dip Card/Cup	250/150/100 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Strip/Cassette/Dip Card/Cup	20 ng/mL	CE
Marijuana (THC) Test	Strip/Cassette/Dip Card/Cup	600/300/200/150/100/50/40/25/20/18/15 ng/mL	CE 510(k)
Methadone Metabolite (EDDP) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Methadone (MTD) Test	Strip/Cassette/Dip Card/Cup	1000/600/300/200/50 ng/mL	CE 510(k)
Methamphetamine (MET) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Methaqualone (MQL) Test	Strip/Cassette/Dip Card/Cup	300/1000 ng/mL	CE
Methcathinone (MTC) Test	Strip/Cassette/Dip Card/Cup	500/300 ng/mL	CE
3,4-Methylenedioxypropylvalerone (MDPV) Test	Strip/Cassette/Dip Card/Cup	1000/500/300 ng/mL	CE
Methylphenidate (MPD) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
6-Monoacetylmorphine (6-MAM) Test	Strip/Cassette/Dip Card/Cup	20/10 ng/mL	CE
Morphine (MOP) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/150/100 ng/mL	CE 510(k)
Opiate (OPI) Test	Strip/Cassette/Dip Card/Cup	2000/300/100 ng/mL	CE 510(k)
Oxycodone (OXY) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Phencyclidine (PCP) Test	Strip/Cassette/Dip Card/Cup	50/25 ng/mL	CE 510(k)
Pinaca Ab (K3) Test	Strip/Cassette/Dip Card/Cup	10 ng/mL	CE
Pregabalin (PGB) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500 ng/mL	CE
Propoxyphene (PPX) Test	Strip/Cassette/Dip Card/Cup	600/300 ng/mL	CE 510(k)
Synthetic Marijuana (K2) Test	Strip/Cassette/Dip Card/Cup	75/50/25/20/10 ng/mL	CE
Tramadol (TRA) Test	Strip/Cassette/Dip Card/Cup	200/100 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Strip/Cassette/Dip Card/Cup	1000/300 ng/mL	CE 510(k)
UR-144 Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	CE
Zolpidem (ZOL) Test ^{New}	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test ^{New}	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test



Product Description	Format	Cut-off Value	Qualification
7-Aminoclonazepam (ACL) Test ^{New}	Device	100 ng/mL	/
Amphetamine (AMP) Test	Device	50/40 ng/mL	CE
Barbiturates (BAR) Test	Device	300/50/30 ng/mL	CE
Benzodiazepines (BZO) Test	Device	50/20/10 ng/mL	CE
Buprenorphine (BUP) Test	Device	10/5 ng/mL	CE
Carisoprodol (SOMA) Test	Device	300 ng/mL	/
Cocaine (COC) Test	Device	50/20 ng/mL	CE
Codeine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Diphenhydramine (DIP) Test ^{New}	Device	150/100 ng/mL	/
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Ethyl Glucuronide (EtG) Test ^{New}	Device	150/100 ng/mL	/
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydrocodone (HCD) Test ^{New}	Device	10 ng/mL	/
Hydromorphone (HMO) Test ^{New}	Device	300/150 ng/mL	/
Ketamine (KET) Test	Device	100/50 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Device	25/10 ng/mL	CE
Marijuana (THC) Test	Device	50/40/30/25/15/12/10/5/4/3 ng/mL	CE
Methadone Metabolite (EDDP) Test	Device	20 ng/mL	CE
Mephedrone (MEP) Test ^{New}	Device	50 ng/mL	/
Methadone (MTD) Test	Device	75/50/30 ng/mL	CE

Methamphetamine (MET) Test	Device	50 ng/mL	CE
Methaqualone (MQL) Test	Device	150/100 ng/mL	CE
Methcathinone (MTC) Test	Device	50 ng/mL	/
3,4-Methylenedioxypropylvalerone (MDPV) Test	Device	200/100/50 ng/mL	CE
Methylphenidate (MPD) Test	Device	50 ng/mL	/
6-Monoacetylmorphine (6-MAM) Test	Device	25/15/10/5/4 ng/mL	CE
Morphine (MOP) Test	Device	15 ng/mL	CE
Opiate (OPI) Test	Device	50/40 ng/mL	CE
Oxycodone (OXY) Test	Device	50/40/20 ng/mL	CE
Phencyclidine (PCP) Test	Device	10 ng/mL	CE
Phenytoloin (PHEN) Test ^{New}	Device	150/100 ng/mL	/
Pinaca Ab (K3) Test ^{New}	Device	10 ng/mL	/
Pregabalin (PGB) Test ^{New}	Device	100 ng/mL	/
Propoxyphene (PPX) Test	Device	50/20 ng/mL	CE
Synthetic Marijuana (K2) Test	Device	25/10/5 ng/mL	CE
Tramadol (TRA) Test	Device	100/50 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Device	100 ng/mL	CE
XLR-11 Test ^{New}	Device	100 ng/mL	/
Zolpidem (ZOL) Test ^{New}	Device	25 ng/mL	/
Zopiclone (ZOP) Test ^{New}	Device	25 ng/mL	/
Alcohol (ALC) Test	Device	0.05/0.02%	CE

Toxicology Hair Test



Product Description	Format	Label	Cut-off Value	Qualification
Amphetamine (AMP) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	Fluorescence	0.2 ng/mg	/
		Gold	1 ng/mg	/
Cocaine (COC) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2 ng/mg	CE
Ecstasy (MDMA) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5 ng/mg	/
2-Fluorodeschloroketamin (FKE) Test	Cassette	Fluorescence	0.2 ng/mg	/
Ketamine (KET) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2/1/0.5 ng/mg	CE
Marijuana (THC) Test	Cassette	Fluorescence	0.05 ng/mg	CE
		Gold	2/1.5 ng/mg	CE
Methamphetamine (MET) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
6-Monoacetylmorphine (6-MAM) Test	Cassette	Gold	2 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Morphine (MOP) Test	Cassette	Gold	5/2/0.5 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Oxycodone (OXY) Test	Cassette	Gold	4 ng/mg	/
		Fluorescence	0.3 ng/mg	CE
Phencyclidine (PCP) Test	Cassette	Gold	1 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Pinaca Ab (K3) Test	Cassette	Gold	0.5 ng/mg	/
		Fluorescence	0.2 ng/mg	CE
Synthetic Marijuana (K2) Test	Cassette	Gold	1 ng/mg	/
Tramadol (TRA) Test	Cassette	Fluorescence	0.2 ng/mg	/
UR-144 Test	Cassette	Fluorescence	0.05 ng/mg	/

Infectious Disease



Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Adenovirus Antigen Test	Swab	GCADE-502a√	Cassette	/	20 Tests/Kit
Adenovirus Test	Feces	GCADE-602a√	Cassette	/	20 Tests/Kit
Brucella Antibody Test	WB/S/P	GCBRU-402a√	Cassette	/	25 Tests/Kit
Candida albicans Test	Vaginal Secretion	GCCA-502a√	Cassette	10 ⁶ CFU/mL	20 Tests/Kit
Chagas Antibody Test	S/P	GCCHA-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHA-402a√	Cassette	/	25 Tests/Kit
Clostridium difficile GDH Test	Feces	GCDD(GDH)-602a√	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCDD(Toxin A/-B)-602a√	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Clostridium difficile GDH & Toxin A/B Combo Test	Feces	GCCD-625a√	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Chikungunya IgM Test	S/P	GCCHK(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHK(IgM)-402a√	Cassette	/	25 Tests/Kit

Chikungunya IgG/IgM Test	WB/S/P	GCCHK(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
Chlamydia Test	Swab/Urine	GCCHL-502a√	Cassette	4.8×10 ³ IFU/mL	20 Tests/Kit
CMV IgG Test	S/P	GCCMV(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG)-402a	Cassette	/	25 Tests/Kit
	S/P	GCCMV(IgM)-302a	Cassette	/	25 Tests/Kit
CMV IgM Test	WB/S/P	GCCMV(IgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCCMV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
CMV IgG/IgM Test	WB/S/P	GCCMV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
COVID-19 IgM/IgG Test	WB/S/P	GCCOV-402a√	Cassette	/	25 Tests/Kit
COVID-19 Neutralizing Antibody Test	WB/S/P	GCCOV(NAB)-402b√	Cassette	/	25 Tests/Kit
		GCCOV-502a√	Cassette	/	20 Tests/Kit
	Nasopharyngeal Swab	GCCOV-502Ca√	Cassette	/	20 Tests/Kit
		GCCOV-501a√ ^{New}	Strip	/	20 Tests/Kit
COVID-19 Antigen Test	Nasal Swab	GCCOV-502a-NA√	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
		GCCOV-503a√ ^{NA}	Device	/	1/2/5/10 Tests/Kit
	NA & NP Swab	GCCOV-502a-NN√	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-702a√	Cassette	/	20 Tests/Kit
		GCCOV-502a-Hxx√	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
COVID-19 Antigen Self-Test	Nasal Swab	GCCOV-502a-HxxOGE√	Cassette	/	1/2/3/5/8/10/15/20/25 Test(s)/Kit
	Oral Fluid	GCCOV-702a-Hxx√ ^{New}	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D503a√ ^{New}	Reader	/	1/2/3/5/7/10/15/20 Test(s)/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCCOV(B117)-525a√	Cassette	/	20 Tests/Kit
COVID-19/Flu A&B/RSV Antigen Combo Test	Nasal Swab	GCFCR-T525a√ ^{New}	Cassette	/	20 Tests/Kit
SARS-CoV-2 Delta-series Mutant Strain Antigen Test	Nasal Swab	GCCOV(Del)-T502a√	Cassette	/	20 Tests/Kit
SARS-CoV-2 Ag Fluorescence Rapid Test	Nasal Swab	FCCOV-502a√ ^{New}	Cassette	/	20 Tests/Kit
Dengue IgG/IgM Antibody Test	WB/S/P	GCDEN(lab)-402c√	Cassette	/	25 Tests/Kit
Dengue NS 1 Antigen Test	WB/S/P	GCDEN(NS)-402c√	Cassette	/	25 Tests/Kit
Dengue NS1 & IgG/IgM Combo Test	WB/S/P	GCDEN-425a√	Cassette	/	20 Tests/Kit
EV71 IgM Test	S/P	GCEV71(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCEV71(IgM)-402a√	Cassette	/	25 Tests/Kit
Giardia lamblia Test	Feces	GCGLA-602a√	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b	Cassette	1.0E+7	20 Tests/Kit
HAV IgM Test	S/P	GCHAV(IgM)-302Ba√	Cassette	/	25 Tests/Kit
HAV IgG/IgM Test	WB/S/P	GCHAV(IgG/IgM)-402a√	Cassette	/	25 Tests/Kit
HAV AntigenTest	Feces	GCHAV-602a√	Cassette	/	25 Tests/Kit
		GCHBcb-302a	Cassette	2 NCU	25 Tests/Kit
HBCAb Hepatitis B Core Antibody Test	S/P	GCHBcb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBcb-402a	Cassette	2 NCU	25 Tests/Kit
		GCHBeb-302a	Cassette	2 NCU	25 Tests/Kit
HBeAb Hepatitis B Envelope Antibody Test	S/P	GCHBeb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBeb-402a	Cassette	2 NCU	25 Tests/Kit
		GCHBeg-302a	Cassette	0.5 NCU	25 Tests/Kit
HBeAg Hepatitis B Envelope Antigen Test	WB/S/P	GCHBeg-402a	Cassette	0.5 NCU	25 Tests/Kit
	S/P	GCHBsb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCHBsb-302a	Cassette	30 mIU/mL	25 Tests/Kit
HBSAb Hepatitis B Surface Antibody Test	S/P	GCHBsb-401a	Strip	30 mIU/mL	50 Tests/Kit
		GCHBsb-402a	Cassette	30 mIU/mL	25 Tests/Kit
		GCHBsb-402b	Cassette	20 mIU/mL	25 Tests/Kit
		GCHBsg-301a	Strip	1 ng/mL	50 Tests/Kit
	S/P	GCHBsg-302a	Cassette	1 ng/mL	25 Tests/Kit
		GCHBsg-401a	Strip	1 ng/mL	50 Tests/Kit
HBSAg Hepatitis B Surface Antigen Rapid Test	WB/S/P	GCHBsg-402a	Cassette	1 ng/mL	25 Tests/Kit
		GCHBC-402a	Cassette	/	25 Tests/Kit
HBSAg/HCV Combo Test	WB/S/P	GCHBCISY-345a	Cassette	/	20 Tests/Kit
HBSAg/HCV/HIV/Syphilis Combo Test	S/P	GCHBCISY-445a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
HBV HBCAb/HBeAb/HBeAg/HBsAb	S/P	GCHBV-455a	Cassette	/	20 Tests/Kit
/HBsAg Combo Test	WB/S/P	GCHCV-301a	Strip	/	50 Tests/Kit
	S/P	GCHCV-302a√	Cassette	/	25 Tests/Kit
HCV Hepatitis C Virus Test		GCHCV-401a	Strip	/	50 Tests/Kit
	WB/S/P	GCHCV-402a√	Cassette	/	25 Tests/Kit
HCV/HIV Combo Test	WB/S/P	GCHCI-402a	Cassette	/	25 Tests/Kit
HEV Hepatitis E Virus IgM Test	S/P	GCHEV-302a√	Cassette	/	25 Tests/Kit
		GCHIV-301a	Strip	/	50 Tests/Kit
	S/P	GCHIV-302a√	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Test		GCHIV-401a	Strip	/	50 Tests/Kit
	WB/S/P	GCHIV-402a√	Cassette	/	25 Tests/Kit
		GCHIV-GT402a	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Tri-line Test	WB/S/P	GCHIV-T302b	Cassette	/	25 Tests/Kit
	S/P	GCHIV-T402a	Cassette	/	25 Tests/Kit
HIV 1/2/O Antibody Test	WB/S/P	GCHIV(Ag/Ab)-402a	Cassette	/	25 Tests/Kit
		GCHSV(IgG)-302a√	Cassette	/	25 Tests/Kit
HIV Antigen/Antibody Combo Test	WB/S/P	GCHSV(IgG)-402a√	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgM)-302a√	Cassette	/	25 Tests/Kit
		GCHSV(IgM)-302a√	Cassette	/	25 Tests/Kit
HSV IgG Test	WB/S/P	GCHSV(IgM)-402a√	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgM)-402a√	Cassette	/	25 Tests/Kit
HSV IgM Test	WB/S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
		GCHSV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCHP-301a√	Strip	/	50 Tests/Kit
		GCHP-302a√	Cassette	/	25 Tests/Kit
		GCHP-401a√	Strip	/	50 Tests/Kit
H. pylori Antibody Test	WB/S/P	GCHP-402a√	Cassette	/	25 Tests/Kit

H. pylori Antigen Test	Feces	GCHP-601a/	Strip	/	25 Tests/Kit	
		GCHP-601Ca/	Strip	/	25 Tests/Kit	
		GCHP-602a/	Cassette	/	20 Tests/Kit	
		GCHP-602Ca/	Cassette	/	20 Tests/Kit	
Influenza A Antigen Test	Nasal/Throat Swabs	GCFLU(A)-501a/	Strip	1.5 x 10 ⁴ TCID ₅₀	25 Tests/Kit	
		GCFLU(A)-502a/	Cassette	1.5 x 10 ⁴ TCID ₅₀	20 Tests/Kit	
Influenza A/B Antigen Test	Nasal/Throat Swabs	GCFLU(A/B)-501a/	Strip	1.5x 10 ⁴ TCID ₅₀ / 1.5 x 10 ⁵ TCID ₅₀	25 Tests/Kit	
		GCFLU(A/B)-502a/	Cassette	1.5x 10 ⁴ TCID ₅₀ / 1.5 x 10 ⁵ TCID ₅₀	20 Tests/Kit	
			GCFLU(A/B)-502Ca/	Cassette	1.5x 10 ⁴ TCID ₅₀ / 1.5 x 10 ⁵ TCID ₅₀	20 Tests/Kit
		Nasopharyngeal Swab	GCFC-525a/	Cassette	/	20 Tests/Kit
Influenza & COVID-19 Antigen Combo Test	NA & NP Swab	GCFC-525a-NN/	Cassette	/	20 Tests/Kit	
		GCFC-525a-NA/	Cassette	/	20 Tests/Kit	
	Nasal Swab	GCFC-7603a/ ^{New}	Cassette	/	1/5/20 Tests/Kit	
		GCFC-7603a/ ^{New}	Device	/	1/2/5/10 Test(s)/Kit	
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFCRA-545a/	Cassette	/	20 Tests/Kit	
	Nasal Swab	GCFCRA-7525a/ ^{New}	Cassette	/	20 Tests/Kit	
Leishmania Antibody Test	S/P	GCKal-301a	Strip	/	50 Tests/Kit	
		GCKal-401a/	Strip	/	50 Tests/Kit	
	WB/S/P	GCKal-402a	Cassette	/	25 Tests/Kit	
		GCKal-7402a/	Cassette	/	25 Tests/Kit	
Malaria Pan Antigen Test	Whole Blood	GMAL(pan)-402a/	Cassette	200 parasites	25 Tests/Kit	
Malaria P.I. Antigen Test	Whole Blood	GMAL(pI)-402a/	Cassette	200 parasites	25 Tests/Kit	
Malaria P.I./Pan Antigen Test	Whole Blood	GMAL(pI/pan)-402a/	Cassette	200 parasites	25 Tests/Kit	
Malaria P.I./P.v. Antigen Test	Whole Blood	GMAL(pI/pv)-402a/	Cassette	200 parasites	25 Tests/Kit	
Malaria P.I./P.v. Antibody Test	S/P	GMAL(pI/pv Ab)-302a/	Cassette	/	25 Tests/Kit	
Monkeypox IgG/IgM Antibody Test	WB/S/P	GMAL(pI/pv Ab)-402a/	Cassette	/	25 Tests/Kit	
Monkeypox Antigen Test	WB/S/P	GCMKP-402a/ ^{New}	Cassette	/	25 Tests/Kit	
Monkeypox Antigen Test	WB/S/P or Throat swab	GCMKP-502a/ ^{New}	Cassette	/	25 Tests/Kit	
Mononucleosis Test	S/P	GCMON-325a/	Cassette	/	25 Tests/Kit	
		GCMON-402a/	Cassette	/	25 Tests/Kit	
	WB/S/P	GCMON-425a/	Cassette	/	25 Tests/Kit	
		GCMON-425a/	Cassette	/	25 Tests/Kit	
M. pneumonia IgM Test	S/P	GCMP(IgM)-302a/	Cassette	/	25 Tests/Kit	
Respiratory Syncytial Virus Antigen Test	Swab	GCRSV-502a/	Cassette	/	20 Tests/Kit	
Rotavirus Test	Feces	GCROA-602a/	Cassette	/	25 Tests/Kit	
Rotavirus/Adenovirus Test		GCROA/ADE-602a/	Cassette	/	25 Tests/Kit	
Rubella IgG Test	S/P	GCRUB(IgG)-302a	Cassette	/	25 Tests/Kit	
	WB/S/P	GCRUB(IgG)-402a	Cassette	/	25 Tests/Kit	
Rubella IgM Test	S/P	GCRUB(IgM)-302a	Cassette	/	25 Tests/Kit	
	WB/S/P	GCRUB(IgM)-402a	Cassette	/	25 Tests/Kit	
	S/P	GCRUB(IgG/IgM)-302a	Cassette	/	25 Tests/Kit	
Rubella IgG/IgM Test	WB/S/P	GCRUB(IgG/IgM)-402a	Cassette	/	25 Tests/Kit	
		GCRUB(IgG/IgM)-7402a	Cassette	/	25 Tests/Kit	
Strep A Test	Throat Swab	GCSTR-501a/	Strip	/	25 Tests/Kit	
		GCSTR-501Ca/†	Strip	/	25 Tests/Kit	
		GCSTR-502a/	Cassette	/	20 Tests/Kit	
		GCSTR-502Ca/	Cassette	/	20 Tests/Kit	
Syphilis Test	S/P	GCSYP-301a/	Strip	/	50 Tests/Kit	
		GCSYP-302a/	Cassette	/	25 Tests/Kit	
		GCSYP-401a/	Strip	/	50 Tests/Kit	
		GCSYP-402a/	Cassette	/	25 Tests/Kit	
S. typhi Antigen Test	S/P/Feces	GC/SAL(ST)-602a/	Cassette	/	20 Tests/Kit	
TOXO IgG Test	S/P	GCTOX(IgG)-302a/	Cassette	/	25 Tests/Kit	
	WB/S/P	GCTOX(IgG)-402a	Cassette	/	25 Tests/Kit	
TOXO IgM Test	S/P	GCTOXO(IgM)-302a/	Cassette	/	25 Tests/Kit	
	WB/S/P	GCTOXO(IgM)-402a	Cassette	/	25 Tests/Kit	
Toxo IgG/IgM Test	S/P	GCTOX-302b	Cassette	/	25 Tests/Kit	
		GCTOX(IgG/IgM)-302a/	Cassette	/	20 Tests/Kit	
ToRCH Toxo/Rubella/CMV/HSV IgG Combo Test	WB/S/P	GCTOX-402b	Cassette	/	25 Tests/Kit	
	S/P	GCTOG-345a	Cassette	/	20 Tests/Kit	
ToRCH Toxo/Rubella/CMV/HSV IgM Combo Test	S/P	GCTOM-345a	Cassette	/	20 Tests/Kit	
Trichomonas vaginalis Test	Vaginal Swab	GCTV-502a/	Cassette	/	20 Tests/Kit	
Tuberculosis IgG/IgM Test	S/P	GCTB-302a/	Cassette	/	25 Tests/Kit	
	WB/S/P	GCTB-402a/	Cassette	/	25 Tests/Kit	
Typhoid IgG/IgM Test	S/P	GCTYP-301a	Strip	/	50 Tests/Kit	
		GCTYP-302a/	Cassette	/	25 Tests/Kit	
V. cholerae O1 Antigen Test	Feces	GCVCH(O1)-602a/	Cassette	/	25 Tests/Kit	
V. cholerae O1/O139 Antigen Test	Feces	GCVCH(O1/O9)-602a/	Cassette	/	25 Tests/Kit	
ZIKA IgM Test	WB/S/P	GCZIK(IgM)-402a	Cassette	/	25 Tests/Kit	
ZIKA IgG Test	WB/S/P	GCZIK(IgG)-402a	Cassette	/	25 Tests/Kit	
ZIKA NS1 Test	WB/S/P	GCZIK(NS1)-402a	Cassette	/	25 Tests/Kit	

Fertility

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
hCG Pregnancy Test	Urine	GAHCG-101a/†	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-101b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-101d/	Strip	20 mIU/mL	100 Tests/Kit
		GAHCG-102a/†	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-102b/	Cassette	10 mIU/mL	25 Tests/Kit
		GAHCG-102d/	Cassette	20 mIU/mL	25 Tests/Kit
		GAHCG-103a/†	Midstream	25 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103b/	Midstream	10 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103d/	Midstream	20 mIU/mL	1/2 Test(s)/Kit
		GAHCG-105a	Panel	25 mIU/mL	25 Tests/Kit
	Urine/Serum	GAHCG-201a/	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-201b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-202a/	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-202b/	Cassette	10 mIU/mL	25 Tests/Kit
Digital Pregnancy Test	Urine	GAHCG-D103a/	Midstream	25 mIU/mL	1/2 Test(s)/Kit
LH Ovulation Test	Urine	GALH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GALH-101b/	Strip	40 mIU/mL	100 Tests/Kit
		GALH-101d	Strip	30 mIU/mL	100 Tests/Kit
		GALH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
		GALH-102b/	Cassette	40 mIU/mL	25 Tests/Kit
		GALH-103a/	Midstream	25 mIU/mL	1/5 Test(s)/Kit
		GALH-103b/	Midstream	40 mIU/mL	1/5 Test(s)/Kit
		GALH-103d	Midstream	30 mIU/mL	1/5 Test(s)/Kit
FSH Menopause Test	Urine	GAFSH-101a/	Strip	25 mIU/mL	100 Tests/Kit
IGFBP-1 PROM Test	Cervical Secretion	GAIGF1-501a/	Strip	25 ng/mL	25 Tests/Kit
		GAIGF1-502a/	Cassette	25 ng/mL	20 Tests/Kit
Male Fertility Test	Semen	GASPE-002a/	Cassette	15M/mL	1 Test/Kit

Cardiac Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
CK-MB Test	S/P	GDCKM-302a/	Cassette	5 ng/mL	25 Tests/Kit
CRP C-Reactive Protein Semi-Quantitative Test	WB/S/P	GDCKM-402a/	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GDGRP-402a/	Cassette	1~3~10 mg/L	25 Tests/Kit
D-dimer Test	WB/P	GDGDI-402b/	Cassette	10~40~80 ng/mL	25 Tests/Kit
Myoglobin Test	WB/S/P	GDIMO-402a/	Cassette	500 ng/mL	25 Tests/Kit
Procalcitonin Test	WB/S/P	GDPCIT-402a/	Cassette	50 ng/mL	25 Tests/Kit
Troponin I Test	S/P	GDTR-302a/	Cassette	0.5~2~10 ng/mL	25 Tests/Kit
	WB/S/P	GDTR-402a/	Cassette	0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDTR-402b/	Cassette	0.5 ng/mL	25 Tests/Kit
Cardiac Myoglobin/CK-MB/CTnI Combo Test	S/P	GDCA-335a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDCA-435a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
		GDCA-W435a/	Cassette	50/5/0.5 ng/mL	20 Tests/Kit

Urinalysis

Product Description	Specimen	Format	Cut-off Value	Kit Size
Ascorbate/†	Urine	Strip	0.5-0.6 mmol/L	100 Tests/Canister
Bilirubin/†	Urine	Strip	8.6-17 µmol/L	100 Tests/Canister
Blood/†	Urine	Strip	5-15 Ery/µL	100 Tests/Canister
Ca/	Urine	Strip	2.5 mmol/L	100 Tests/Canister
Creatinine/	Urine	Strip	50 mg/dL	100 Tests/Canister
Glucose/†	Urine	Strip	2.8~5.5 mmol/L	100 Tests/Canister
Ketone/†	Urine	Strip	0.5~1.0 mmol/L	100 Tests/Canister
Leukocytes/†	Urine	Strip	5-15 Leuko/µL	100 Tests/Canister
Micro Albumin/	Urine	Strip	0.08~0.15 mg/dL	100 Tests/Canister
Nitrite/†	Urine	Strip	13~22 µmol/L	100 Tests/Canister
pH/†	Urine	Strip	0.5	100 Tests/Canister
Protein/†	Urine	Strip	0.15~0.3 g/L	100 Tests/Canister
Specific Gravity/†	Urine	Strip	0.005	100 Tests/Canister
Urobilinogen/†	Urine	Strip	3.3-16 µmol/L	100 Tests/Canister
Urinary Tract Infection Test Strip	Urine	Strip	LEU: 10-15 Leuko/µL NIT: 13-22 µmol/L	3 Tests/Kit

Tumor Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
AFP Alpha Fetal Protein Test	S/P	GEAFP-301a	Strip	20 ng/mL	50 Tests/Kit
	WB/S/P	GEAFP-302a/	Cassette	20 ng/mL	25 Tests/Kit
CEA Carcinoembryonic Antigen Test	S/P	GEAFP-401a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-402a/	Cassette	20 ng/mL	25 Tests/Kit
	WB/S/P	GECEA-301a	Strip	5 ng/mL	50 Tests/Kit
		GECEA-302a	Cassette	5 ng/mL	25 Tests/Kit
		GECEA-401a/	Strip	5 ng/mL	50 Tests/Kit
		GECEA-402a/	Cassette	5 ng/mL	25 Tests/Kit
		GEFOB-601b/†	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601Cb/	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601c/	Strip	100 ng/mL	25 Tests/Kit
		GEFOB-601d	Strip	200 ng/mL	25 Tests/Kit
FOB Fecal Occult Blood Test	Feces	GEFOB-602b/†	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602Cb/	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602c/	Cassette	100 ng/mL	20 Tests/Kit
		GEFOB-602d	Cassette	200 ng/mL	20 Tests/Kit
		GEFOB-602h	Cassette	150 ng/mL	20 Tests/Kit
		GEFOB-602j/	Cassette	10 ng/mL	20 Tests/Kit
		GEFOB/TF-602a/	Cassette	50/10 ng/mL	20 Tests/Kit
		GENMP22-102a/ ^{New}	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate Specific Antigen Test	S/P	GEPSA-301a/	Strip	4 ng/mL	50 Tests/Kit
	WB/S/P	GEPSA-302a/	Cassette	4 ng/mL	25 Tests/Kit
		GEPSA-401a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a/	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-Quantitative Test	S/P	GEPSA-302b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-402b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
Transferrin Test	Feces	GETF-601a/	Strip	10 ng/mL	25 Tests/Kit
		GETF-602a/	Cassette	10 ng/mL	20 Tests/Kit

Veterinary

Product Description	Specimen	Catalog No.	Format	Label	Cut-off Value	Kit Size
Canine Adenovirus (CAV) Antigen Test	Secretions	GFCAV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Coronavirus (CCV) Antigen Test	Feces	GFCCV-602a	Cassette	Gold	/	10 Tests/Kit
		FFCCV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Coronavirus (CCV) & Parvovirus (CPV) Antigen Combo Test	Feces	GFCCP-T602a	Cassette	Gold	/	10 Tests/Kit
Canine C-Reactive Protein (cCRP) Test	WB/S/P	FFCCR-402a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Distemper Virus (CDV) Antigen Test	Secretions	GFCDV-502a	Cassette	Gold	/	10 Tests/Kit
		FFCDV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Distemper Virus (CDV), Influenza Virus (CIV) & Adenovirus (CAV) Antigen Combo Test	Secretions	GFCDIA-532a	Cassette	Gold	/	10 Tests/Kit
Canine Influenza Virus (CIV) Antigen Test	Secretions	GFClV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	Feces	GFPCV-602a	Cassette	Gold	/	10 Tests/Kit
Canine Progesterone (cProg) Test	WB/S/P	FFCPR-402a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Calicivirus (FCV) Antigen Test	Secretions	GFFCV-502a	Cassette	Gold	/	10 Tests/Kit
Feline Coronavirus (FCoV) Antigen Test	Feces	GFFCV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Herpes Virus (FHV) Antigen Test	Secretions	GFFHV-502a	Cassette	Gold	/	10 Tests/Kit
		FFHHV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) Antigen Test	Feces	GFFPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFFPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test	Feces	GFFPC-622a	Cassette	Gold	/	10 Tests/Kit
Feline Serum Amyloid A (fSAA) Test	WB/S/P	FFESA-402a	Cassette	Fluorescence	5 mg/L	10 Tests/Kit
Toxoplasma (Toxo) IgG/IgM Test	WB/S/P	GFTOX-402a	Cassette	Gold	/	10 Tests/Kit

Non-Infectious Disease

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Micro-Albumin Test	Urine	GIHSA-101a/	Strip	20 µg/mL	100 Tests/Kit
Vaginal pH Test	Vaginal Secretion	GIHSA-102a	Cassette	20 µg/mL	25 Tests/Kit
		VPH-501a ^{New}	Strip	3.8-4.4	100 Tests/Canister

Autoimmunity

Product Description	Specimen	Catalog No.	Format	Kit Size
Rheumatoid Factor IgM Test	S/P	GCRF(IgM)-302a	Cassette	25 Tests/Kit
Total IgE Test	S/P	GCIGE-302a	Cassette	25 Tests/Kit

Instrument

Product Description	Model
Urine Analyzer	Healgen 500/
Urine Analyzer	Healgen 501/
Colloidal Gold Test Reader	OG-D180
Handheld Oral Fluid Drug Test Reader	OG-D200
Multi-Function Colloidal Gold Test Reader	OG-D600
Fluorescence Immunoassay Analyzer	OG-G200
Handheld Fluorescence Immunoassay Analyzer	OG-G300
Mini Immunofluorescence Analyzer	OG-H100/
Veterinary Fluorescence Immunoassay Analyzer	OG-V100

✓CE Marked

†Cleared for US 510(k)

In Specimen column: WB: Whole Blood

S: Serum

P: Plasma



Zhejiang Orient Gene Biotech Co., Ltd was founded in December 2005 and listed on the SEE STAR Market on February 5, 2020 (securities code: 688298). Orient Gene specializes in R&D, production and sales of in vitro diagnostic products, mainly covering infectious diseases (including COVID-19 test series), toxicology, tumor markers, cardiac markers and fertility testing, etc. Through 16 years of technology accumulation and continuous investment in R&D, the Company has independently developed hundreds of products. The company own more than 200 authorized patents, and has obtained more than 500 product medical device certifications at home and abroad. The Company's sales network covers more than 100 countries, products are mainly sold to Europe, America and other developed countries.

Healgen Scientific LLC, a wholly owned subsidiary of Zhejiang Orient Gene Biotech Co., Ltd develops, manufactures and commercializes in vitro diagnostic test systems worldwide. Our product portfolio spans multiple testing categories and analytes to meet various clinical and laboratory needs.

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PRODUCT CATALOG

Enhancing
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