



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:

A handwritten signature in black ink, appearing to read "Xie", is written over a horizontal line.

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



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.



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

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**

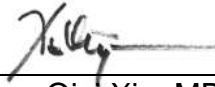
**The declaration according to Annex IV of the Directive
is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission**

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.





ACON Laboratories, Inc.

10125 Mesa Rim Road. • San Diego, CA 92121 • USA
Tel: (858) 875-8000 • Fax: (858) 875-8099 • E-mail: info@aconlabs.com

November 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

A handwritten signature in black ink, appearing to read "Jassy Alvarenga", is written over a red circular stamp.



Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc. S.A.
jalvarenga@aconlabs.com
+1 858 875 8085

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 medical device:

Mission® Lancets (C121-3041)
On Call® Lancets (G124-10A)
Insight® Lancets (C121-3045)
Swiss Point of Care Lancets (G124-90AA)

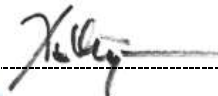
**of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,
meets all the provisions of the directive 93/42/EEC as amended by directive
2007/47/EC concerning medical devices which apply to it.**

**This declaration is according to Annex II of the Directive and thus 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. G1 104507 0002 Rev. 01
Expiration Date: 2023-09-06

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

Signed this 17 day of August, 2021
in San Diego, CA USA



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



Declaration of Conformity

We, the manufacturer, under compliance to Article 19 of EU MDR 2017/745, declare under our sole responsibility that the medical device:

Mission® Lancing Device (C121-3051)
Insight® Lancing Device (C121-3055)
On Call® Lancing Device (G124-11A)
On Call® GenTouch Lancing Device (G124-17A)
Swiss Point of Care Lancing Device (G124-91AA)
GIMA Lancing Device (G124-91AC)
Go-Keto Lancing Device (G124-97AA)

**of class I according to Rule 13 of Annex VIII of regulation (EU) 2017/745,
is in conformity with EU MDR 2017/745.**

This declaration is based on:

Manufacturer's Name: ACON Laboratories, Inc.

Manufacturer's Address: 5850 Oberlin Drive, #340 San Diego, CA 92121

Manufacturer's SRN: US-MF-000023913

Authorized Representative Name: Medical Device Safety Service GmbH

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI: 826079999900013V

Intended Purpose of device: The device is intended for injuring the fingertip in combination with a disposable lancet for obtaining a small amount of blood sample.

Signed this 18 day of May 2022
in San Diego, CA USA



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



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.



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)

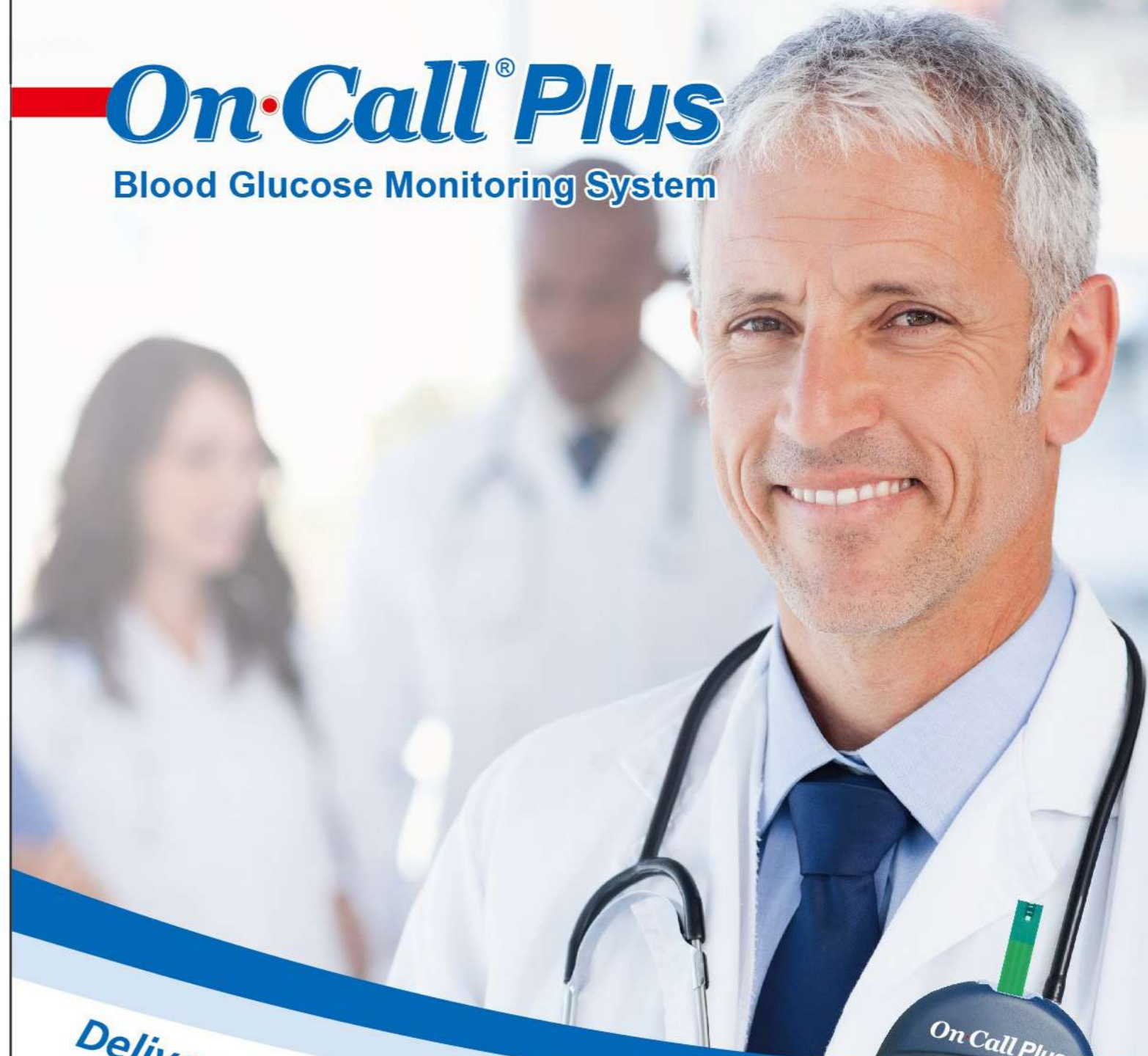
Catalog

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



On-Call[®] Plus
Blood Glucose Monitoring System



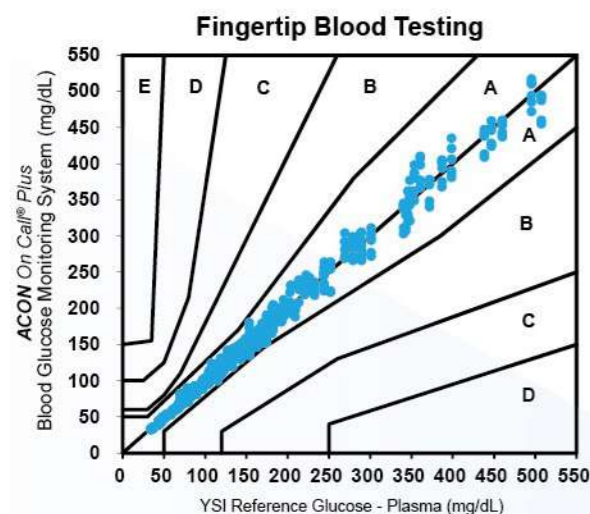
Delivers Value and Quality

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

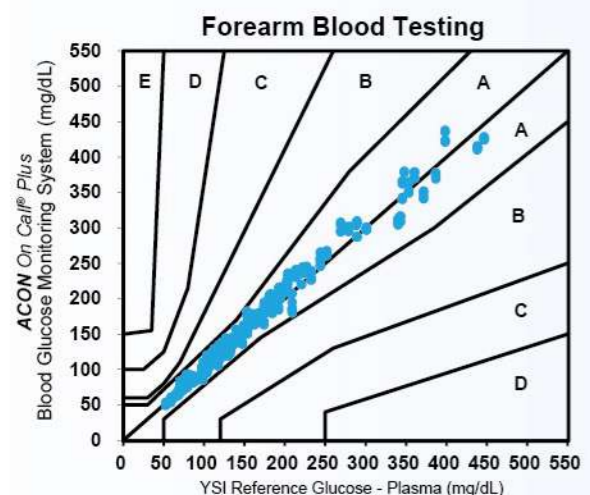


Accurate and Reliable

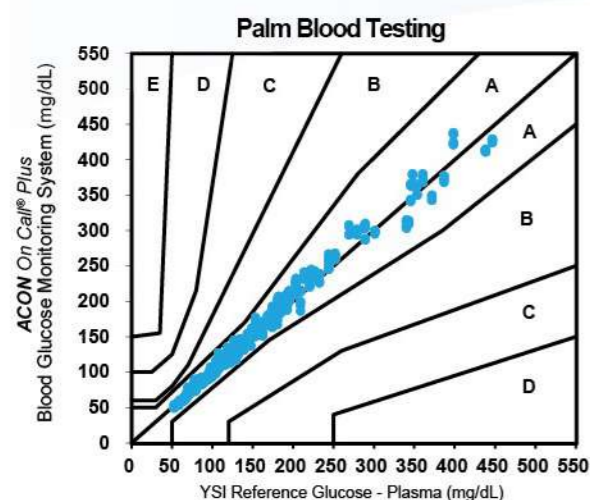
Extensive clinical studies proved the accuracy of *On Call Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



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 $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 15\%$ or ± 15 mg/dL		
658 / 660 (99.7%)		



Consensus Error Grid Analysis Clinical Trial - Forearm Capillary Blood, by Technican ACON On Call Plus Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 15\%$ 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 $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 15\%$ or ± 15 mg/dL		
609 / 612 (99.5%)		

Key Features

0.5 μ L blood sample

HCT 25 - 60% HCT range

2 - 35°C strip storage temperature

Optional individually packaged test strips available

Alternative testing sites including fingertip, forearm and palm

Automatic detection of insufficient sample

300 test memory with date and time

7, 14, 30 - day averages calculation

Easy PC data transfer and smart App data analysis

Authority Certificate



Letter of Authorization

To whom it may concern,

We, **Getein Biotech, Inc.** (No.9 Bofu Road, Luhe District, Nanjing, 211505, China), hereby authorize Sanmedico SRL (Address: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10) as our official and non-exclusive distributor for registration, promoting, selling, distributing and providing after-sale services of under-mentioned product in the territory of Moldova only:

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

Sanmedico SRL will comply with the laws and regulations of the countries and regions where they are located in and where they are selling mentioned product.

Sanmedico SRL will carry out marketing efforts to fulfill service and maintenance for above mentioned products and will provide with users benefits of having a local stock of above mentioned products and on-time delivery with every order, supported by a local service in local language.

This authorization starts from **1st Jan, 2024** and will be valid to **31th, December, 2024** .

Getein Biotech, Inc. has the right to terminate the authorization before validity and will inform Sanmedico SRL with 10 days in advance.


基蛋生物科技股份有限公司
Getein Biotech, Inc.
GETEIN BIOTECH, INC.
Seal & Signature

Authority Person Name: **Steven Zhou**

Authority Person Position: **Regional Manager**

Date: **2023.12.13**

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Getein Biotech, Inc.**
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编: 211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.

研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。



Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.

Certificate No: **MD 728432**

Location	Registered Activities
<p>Getein Biotech, Inc. No.9 Bofu Road Luhe District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京市 六合区 沿江工业开发区 博富路9号 邮编: 211505</p>	<p>Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.</p> <p>研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。</p>
<p>Getein Biotech, Inc. No. 6 KeFeng Road Jiangbei New District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京 江北新区 科丰路6号 邮编: 211505</p>	<p>Manufacture of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), Colloidal Gold self-testing Assay to detect infectious disease. Manufacture of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.</p> <p>生产化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂和传染病相关胶体金自测试剂。 生产用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。</p>

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

Page: 3 of 3

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Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.

EC Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Ref. No.:20220513-A05

Manufacturer
(Name, Address)

Getein Biotech, Inc.
No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

Authorized Representative
(Name, Address)

CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Medical device

No.	Product Name
1	Getein 1100 Immunofluorescence Quantitative Analyzer
2	Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)
3	NT-proBNP Fast Test Kit (Immunofluorescence Assay)
4	hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)
5	NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)
6	CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
7	D-Dimer Fast Test Kit (Immunofluorescence Assay)
8	PCT Fast Test Kit (Immunofluorescence Assay)
9	CysC Fast Test Kit (Immunofluorescence Assay)
10	mAlb Fast Test Kit (Immunofluorescence Assay)
11	NGAL Fast Test Kit (Immunofluorescence Assay)
12	β 2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+ β Fast Test Kit (Immunofluorescence Assay)
15	H-FABP Fast Test Kit (Immunofluorescence Assay)
16	PCT/CRP Fast Test Kit (Immunofluorescence Assay)
17	CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)
18	HbA1c Fast Test Kit (Immunofluorescence Assay)
19	NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay)
20	CK-MB Fast Test Kit (Immunofluorescence Assay)
21	hs-cTnI Fast Test Kit (Immunofluorescence Assay)
22	T3 Fast Test Kit (Immunofluorescence Assay)
23	T4 Fast Test Kit (Immunofluorescence Assay)
24	TSH Fast Test Kit (Immunofluorescence Assay)
25	Scr Fast Test Kit (Immunofluorescence Assay)
26	PLGF Fast Test Kit (Immunofluorescence Assay)



- 27 HCY Fast Test Kit (Immunofluorescence Assay)
- 28 Anti-CCP Fast Test Kit (Immunofluorescence Assay)
- 29 25-OH-VD Fast Test Kit (Immunofluorescence Assay)
- 30 Lp-PLA2 Fast Test Kit (Immunofluorescence Assay)
- 31 FOB Fast Test Kit (Immunofluorescence Assay)
- 32 SAA Fast Test Kit (Immunofluorescence Assay)
- 33 H. pylori Fast Test Kit (Immunofluorescence Assay)
- 34 PRL Fast Test Kit (Immunofluorescence Assay)
- 35 Transferrin Fast Test Kit (Immunofluorescence Assay)
- 36 Insulin Fast Test Kit (Immunofluorescence Assay)
- 37 PG I /PG II Fast Test Kit (Immunofluorescence Assay)
- 38 LH Fast Test Kit (Immunofluorescence Assay)
- 39 FSH Fast Test Kit (Immunofluorescence Assay)
- 40 Anti-TP Fast Test Kit (Immunofluorescence Assay)
- 41 AFP/CEA Fast Test Kit (Immunofluorescence Assay)
- 42 AMH Fast Test Kit (Immunofluorescence Assay)
- 43 fT3 Fast Test Kit (Immunofluorescence Assay)
- 44 fT4 Fast Test Kit (Immunofluorescence Assay)
- 45 Total IgE Fast Test Kit (Immunofluorescence Assay)
- 46 Vit-B12 Fast Test Kit (Immunofluorescence Assay)
- 47 Prog Fast Test Kit (Immunofluorescence Assay)
- 48 Testosterone Fast Test Kit (Immunofluorescence Assay)
- 49 E2 Fast Test Kit (Immunofluorescence Assay)
- 50 RF Fast Test Kit (Immunofluorescence Assay)
- 51 ASO Fast Test Kit (Immunofluorescence Assay)
- 52 Ferritin Fast Test Kit (Immunofluorescence Assay)
- 53 ST2 Fast Test Kit (Immunofluorescence Assay)
- 54 CA125 Fast Test Kit (Immunofluorescence Assay)
- 55 CA19-9 Fast Test Kit (Immunofluorescence Assay)
- 56 CA15-3 Fast Test Kit (Immunofluorescence Assay)
- 57 RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)
- 58 Influenza A/B Fast Test Kit (Immunofluorescence Assay)
- 59 RSV Fast Test Kit (Immunofluorescence Assay)
- 60 IL-6 Fast Test Kit (Immunofluorescence Assay)
- 61 BNP Fast Test Kit (Immunofluorescence Assay)
- 62 SAA/CRP Fast Test Kit (Immunofluorescence Assay)
- 63 Folate acid Fast Test Kit (Immunofluorescence Assay)
- 64 hs-CRP Fast Test Kit (Immunofluorescence Assay)
- 65 TnT Fast Test Kit (Immunofluorescence Assay)
- 66 PCT/IL-6 Fast Test Kit (Immunofluorescence Assay)



- 67 HBP Fast Test Kit (Immunofluorescence Assay)
- 68 S100-β Fast Test Kit (Immunofluorescence Assay)
- 69 CK-MB/hs-cTnl/Myo Fast Test Kit (Immunofluorescence Assay)
- 70 Cortisol Fast Test Kit (Immunofluorescence Assay)
- 71 CEA Fast Test Kit (Immunofluorescence Assay)
- 72 AFP/CEA Fast Test Kit (Immunofluorescence Assay)

Classification Other device (according to Annex II of the directive 98/79/EC)

Conformity assessment route Annex III of the 98/79/EC

Applicable coordination standards	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
	EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015
	EN 61326-2-6:2006	IEC 61326-1:2013	
	EN 61010-2-101:2002	IEC 61010-1:2010	

Signatory representative declares herein the above-mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex I.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing
13th, May, 2022
 (place and date of issue)

Enben Su
 (name and signature or equivalent marking of authorized person)



CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

Completion of Getein Products Technical and Operational Training
& Qualification of After-sales Service

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.



Cardiac
Markers

Coagulation
Markers

Diabetes
Mellitus

Inflammation

Thyroid
Function

Metabolic
Marker

Renal
Function

Tumor
Markers

Reproduction
/Fertility

Infectious
Disease



Getein
Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

MAKING TEST EASY

Getein 1100

Immunofluorescence Quantitative Analyzer



Getein 1100

Immunofluorescence Quantitative Analyzer



HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



REAL-TIME AND RAPID TEST

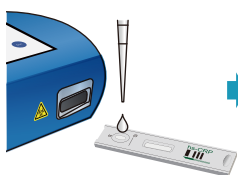
One-step test

3-15 min/test

5 sec/test for multiple tests

OPERATION MODES

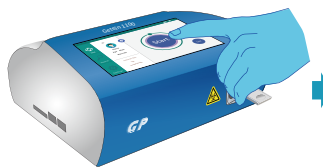
Inside Mode (single sample rapid test mode)



Sample Transfer



Test Card Insert



Click "Start" Icon

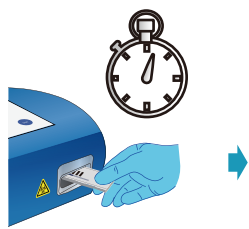


Result Show and Print

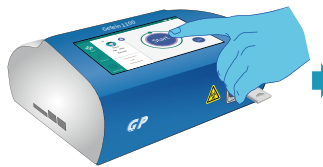
Quick mode (mass samples rapid test mode)



Sample Transfer



Timing the Reaction Manually



Click "Start" Icon



Result Show and Print



CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

Handwriting input available

Continuous test for 3 hours with optional lithium battery



USER-FRIENDLY INTERFACE

Android system

7-inch touch screen



1 7-inch Touch Screen

3 Test Card Slot

5 USB Slot

2 SD Card Recognition Zone

4 SD Card Slot

6 Built-in Thermal Printer



PORTABLE DESIGN

Small in size: 261 × 241 × 115 mm

Light in weight: 2.0 kg



LARGE MEMORY

Up to 10,000 results storage capacity

TECHNICAL PARAMETERS

Methodology	Immunofluorescence	Screen	7-inch touch screen
Result	Quantitative	Power Supply	100-240 V~50 Hz/60 Hz, 60 VA
Sample Type	WB, Plasma, Serum, Urine, Stool, Nasal swab, Saliva, Capillary blood	Working Environment	Temperature: 10-35°C Relative humidity ≤ 70% Air pressure 70.0~106.0 kpa
Storage Capacity	10000 data	Dimensions	261 mm×241 mm×115 mm (D×W×H)
Language	English/Chinese/Spanish/Portuguese	Weight	2.0 kg

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Cardiac Markers								
IF1001	cTnI	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	100 µL	10 min	NMPA CE
NEW IF1098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	NMPA CE
IF1089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA CE
IF1002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA CE
IF1005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL Myo: 70.0 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA CE
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL	100 µL	10 min	CE
IF1014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	100 µL	3 min	NMPA CE
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 2.00-100.00 ng/mL	100 µL	10 min	NMPA CE
IF1018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	CE
Coagulation Marker								
IF1006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	100 µL	10 min	NMPA CE
Inflammation								
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3.0 mg/L 10.0 mg/L	S/P/WB/ Fingertip blood	0.5-200.0 mg/L	10 µL	3 min	NMPA CE
IF1007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 min	NMPA CE
IF1015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.10 ng/mL CRP: 3.0 mg/L	S/P/WB	0.10-50.00 ng/mL 0.5-200.0 mg/L	100 µL	15 min	NMPA CE
IF1044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA CE
IF1090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA CE
IF1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	100 µL	15 min	NMPA CE
Renal Function								
IF1008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	10 µL	3 min	NMPA CE
IF1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA CE
IF1010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	10 µL	10 min	NMPA CE
IF1011	β ₂ -MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA CE
Diabetes Mellitus								
IF1017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NGSP NMPA IFCC CE
Metabolic Marker								
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P	8.00-70.00 ng/mL	40 µL	15 min	NMPA CE
Thyroid Function								
IF1024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA CE
IF1022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	40 µL	15 min	NMPA CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA CE
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	CE
IF1068	fT4	Hyperthyroidism, hypothyroidism	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	100 µL	15 min	CE

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Reproduction/Fertility								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	100 μL	10 min	NMPA CE
IF1055	LH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	200 μL	15 min	CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 μL	15 min	NMPA CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
NEW IF1073	Testosterone	Female polycystic ovary syndrome, male testosterone insufficiency	Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL	S/P	0.10-16.00 ng/mL	100 μL	15 min	CE
NEW IF1074	E2	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	100 μL	15 min	CE
Tumor Markers								
IF1053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.50-100.00 ng/mL	100 μL	15 min	NMPA
IF1072	fPSA	Prostate cancer	1.00 ng/mL	S/P	0.05-30.00 ng/mL	100 μL	10 min	NMPA
IF1050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF1058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	100 μL	15 min	CE
IF1059	Anti-HIV	AIDS	1.00 S/CO	S/P	1.00-1000.00 S/CO	100 μL	15 min	
IF1064	HBsAg	Hepatitis B	1.00 IU/mL	S/P	1.00-100.00 IU/mL	100 μL	15 min	
NEW IF1063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 μL	15 min	
IF1084	2019-nCoV IgM/IgG	COVID-19	1.00 COI	S/P/WB		100 μL	10 min	CE
NEW IF1091	SARS-CoV-2 Antigen	COVID-19	1.00 COI	Nasal swab/Saliva		100 μL	15 min	CE
NEW IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB/ Fingertip blood		40 μL	15 min	CE
IF1047	<i>H. pylori</i>	<i>H. pylori</i> infection	5.0 ng/mL	Stool	1.0-200.0 ng/mL	3 drops (about 100 μL)	10 min	CE
NEW IF1086	Influenza A/B	Respiratory viral infection	1.00 S/CO	Nasal swab		100 μL	15 min	CE
NEW IF1136	Dengue NS1 Ag	Dengue virus infection	1.00 S/CO	S/P/WB	0.50-50.00 S/CO	100 μL	15 min	CE
Specific Protein and Rheumatism								
NEW IF1075	RF	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	10 μL	10 min	CE
NEW IF1076	ASO	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	408.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 μL	10 min	CE
NEW IF1029	Anti-CCP	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	10 μL	15 min	CE
Others								
NEW IF1077	Ferritin	Anemia/tumors	Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL	S/P	0.50-1000.00 ng/mL	10 μL	15 min	CE
NEW IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE
NEW IF1052	PG I/PG II	Atrophic gastritis, stomach cancer	PG I < 70.0 ng/mL PG I/PG II < 3.0 ng/mL	S/P	PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL	100 μL	15 min	

Coming Soon: FOB, Folate...

GP Getein Biotech, Inc.

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 E-mail: sales@getein.com.cn; overseas@getein.com.cn
 Web.: www.getein.com

ISO FSC CE NMPA NGSP IFCC IVD





CK-MB/cTnI/Myo Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1005
Getein1600: Cat.# IF2005

INTENDED USE

CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB/cTnI/Myo in serum, plasma or whole blood. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

Troponin complex consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another

cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardia.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

Myoglobin is a small monomeric protein which serves as an intracellular oxygen storage site. It is found in abundance in the muscle and can get through into the blood circulation directly when myocardial cell is damaged mildly. Therefore, myoglobin has been advocated as a sensitive marker for early acute myocardial injury by American College of Cardiology Committee.

PRINCIPLE

Mixed monoclonal antibodies against human CK-MB, cTnI and Myo are conjugated with fluorescence latex and another set of anti-human CK-MB/cTnI/Myo monoclonal antibodies were coated on different test lines respectively. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies will bind with the CK-MB, cTnI and Myo in sample respectively and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by another set of monoclonal antibodies against human CK-MB, cTnI or Myo respectively resulting in the accumulation of fluorescence particles on the test lines. The fluorescence intensity of each test line increases in proportion to the amount of CK-MB, cTnI or Myo in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of CK-MB, cTnI and Myo

in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to LIS and HIS.

CONTENTS

- A kit for Getein1100 contains:
 - Getein CK-MB/cTnI/Myo test card in a sealed pouch with desiccant 25
 - Disposable pipet 25
 - Whole blood buffer 1
 - SD card 1
 - User manual 1
- A kit for Getein1600 contains:
 - Sealed cartridge with 24/48 Getein CK-MB/cTnI/Myo test cards 2
 - User manual 1
 - Package specifications:
 - 2x24 tests/kit, 2x48 tests/kit
 - Materials required for Getein1600:
 - Sample diluent 1
 - Box with pipette tips 1
 - Mixing plate 1
- Sample diluent/Whole blood buffer composition:
 - Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
- A test card consists of:
 - A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies, these three lines are coated with another anti-human CK-MB, another anti-human cTnI and another anti-human Myo monoclonal antibody, respectively, and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0-30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2-8°C for better results.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Do not reuse the test card.
- Do not reuse the pipet.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for *serum, plasma and whole blood samples*. *Heparin and sodium citrate* should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using serum or plasma for better results.
- Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
- If testing will be delayed, serum and plasma samples may

be stored up to 7 days at 2–8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2–8°C).

- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME (for Getein1100): 100 µl.**

TEST PROCEDURE

- Collect specimens according to user manual.
- Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

- Confirm SD card Lot No. in accordance with test kit Lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
- On the main interface of Getein1100, press "ENT" button to enter testing interface.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver **100 µl** of sample (or 3–4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
- Reaction time: 15 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

- Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

- It is required to perform "SD Card Calib" calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein1100.

- Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.0 ng/ml. (The probability that value of a normal person below 5.0 ng/ml is 99%.)

The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)

The expected normal value for Myo was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for Myo is 50 ng/ml. The 97.5th percentile of the concentration for Myo is 70 ng/ml. (According to different Statistics method, the probability that value of a normal person below 50 ng/ml is 95% or below 70 ng/ml is 97.5%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

	CK-MB	cTnI	Myo
Measuring Range	2.5–80,0 ng/ml	0.1–50,0 ng/ml	30,0–600,0 ng/ml
Lower Detection Limit	≤ 2.5 ng/ml	≤ 0.1 ng/ml	≤ 30.0 ng/ml
Within-Run Precision	≤10%		
Between-Run Precision	≤15%		

Method Comparison:

The assay was compared with HITACHI 7600/OLYMPUS AU5400 and its matching CK-MB test kits, SIEMENS IMMULITE 1000/2000 and its matching cTnI and Myo test kits with 200

serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for CK-MB is 0.928, the correlation coefficient (r) for cTnI is 0.952, the correlation coefficient (r) for Myo is 0.938.

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Samples containing interferences may influence the results. The table below listed the maximum allowance of these potential interferences.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L













REFERENCES

- Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887–893.
- Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) are the

most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF09-S-02



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PCT Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1007

Getein1600: Cat.# IF2007

User Manual

INTENDED USE

PCT Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Procalcitonin (PCT) in serum, plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of bacterial infection, trauma or shock.

SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.

Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.

PCT levels may be useful to distinguish bacterial infections from nonbacterial infections. It has shown that PCT may help guide therapy and reduce antibiotic use, which can help save on cost of antibiotic prescriptions and drug resistance.

PRINCIPLE

The test uses an anti-human PCT monoclonal antibody conjugated with fluorescence latex. For PCT product, test line 1 was coated with anti-human PCT polyclonal antibody and test line 2 was coated with another anti-human PCT monoclonal antibody. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human PCT monoclonal antibody binds with the PCT in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen

antibody complex is captured on the test line by the other anti-human PCT monoclonal antibody or the polyclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of PCT in sample. Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of PCT in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
 - Getein PCT test card in a sealed pouch with desiccant 25
 - Disposable pipet 25
 - Whole blood buffer 1
 - SD card 1
 - User manual 1
2. A kit for Getein1600 contains:
 - Sealed cartridge with 24/48 Getein PCT test cards 2
 - User manual 1
 - Package specifications:
 - 2×24 tests/kit, 2×48 tests/kit
 - Materials required for Getein1600:
 - Sample diluent 1
 - Box with pipette tips 1
 - Mixing plate 1
3. Sample diluent/Whole blood buffer composition:
 - Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
 - A plastic shell and a reagent strip which is composed of a sample pad, fluorescence latex pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human PCT monoclonal antibody, the test line are coated with another anti-human PCT monoclonal antibody and polyclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *serum, plasma and whole blood samples*. *Heparin and sodium citrate* should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. **SAMPLE VOLUME (for Getein1100): 100 µl.**

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
 4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
 5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
 6. Put the test card on a clean table, horizontally placed.
 7. Using sample transfer pipette, deliver 100 µl of sample (or 3-4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
 8. **Reaction time: 15 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.
- ### For Getein1600:
9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
 10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD Card Calib" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

The expected normal value for PCT was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.) The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care

Medicine), showing the PCT value and its clinical meaning^[4]:

PCT concentration	Clinical significance
< 0.5 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.5 and < 2.0 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.0 ng/ml	Systemic infection (sepsis) is likely, a high risk of severe sepsis and/or septic shock.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~50.0 ng/ml
Lower Detection Limit	≤0.1 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with Roche MODULAR ANALYTICS E170 automatic immunoassay system and its matching PCT test kits with 200 serum samples (68 positive samples and 132 negative samples). The correlation coefficient (r) for PCT is 0.983.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferent may influence the results. The table below lists the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L













REFERENCES

1. Balci C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanoglu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85-90.
2. Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. Sep 9 2009; 302(10):1059-66.
3. Briel M, Schuetz P, Mueller B, et al. Procalcitonin-guided antibiotic use vs a standard approach for acute respiratory

- tract infections in primary care. Arch Intern Med. Oct 13 2008; 168(18):2000-7; discussion 2007-8.
4. Meisner M. Procalcitonin (PCT) - A New innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.
5. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on PCT Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing PCT Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF06-S-02



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

STATEMENT

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

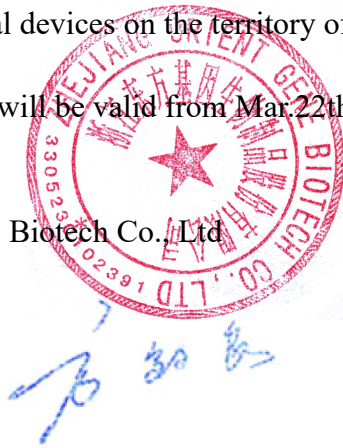
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

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

Zhejiang Orient Gene Biotech Co.,Ltd

General Manager:

Date:2024/3/22



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Certificate

No. Q5 092305 0001 Rev. 02

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

Certification Mark:



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

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

Report No.: SH2398804

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

Date, 2024-03-01



Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 092305 0001 Rev. 02

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

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

See Scope of Certificate



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



CE-DOC-OG054
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

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

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

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

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

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

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

We hereby explicitly appoint

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

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

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

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

Date Signed: November 28, 2017

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

Toxicology Hair Test

Features and Benefits

- **More Convincing Results:** Higher sensitivity compared to urine, saliva, etc.
- **Excellent Support:** Supports a wide range of drugs for testing.

For Analyzer

- ▲ **Fast Test Speed:** Completed single test within 10 seconds.
- ▲ **Fast Information Entry:** Built-in ID recognition.
- ▲ **Instant Print:** Results can be print when the test is done.



OG-G200

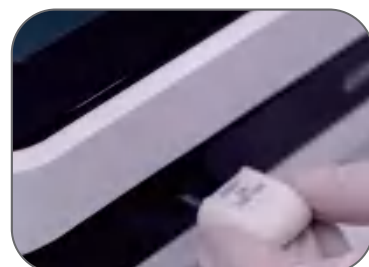
Fluorescence Immunoassay Analyzer



OG-G300

Handheld Fluorescence Immunoassay Analyzer

◆ Test Procedure



Insert the ID card into the ID slot in front of the analyzer, the information of the card will appear on the screen, press "Confirm".



Cut 20 hairs (about 3cm) close to the scalp of the person to be examined, and place the cut hairs on the weighing paper.



Using clean tweezers, place the hair to be tested into a grinding tube and grind with a grinding machine for 2 minutes.



Pour the hair dissolving liquid into the processing cube and shake it well and let it stand for 1 minute.



Absorb 3 drops of the clear hair lysis solution. Then drop it into the sample well of the test cassette.



After 3 minutes of reaction, insert the test cassette into the test slot of the analyzer. Do not interpret result after 5 minutes

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

New Analyzer Coming Soon



Multiplex Fluorescence Analyzer
Apply to Multi-Drug Test Cassette

Model	OG-G260
Display	7 inch touch screen, 1024×600 Pixel
Network	Wi-Fi/BT/3G
Speed	20 seconds/pic
Data Storage	10,000 groups
Thermal Printer	Support, heat sensitivity
CV	5%
Power Supply	12V, 5A
Dimensions	220 mm×278 mm×171 mm
Weight	2.9 kg

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. With hundreds of detection products and supporting biomaterials, the Company has a complete industrial chain layout from the upstream core antigen/antibody biomaterials to the POCT rapid diagnostic reagents and rapid diagnostic instruments. The Company is accelerating the industrial upgrading from 'product provider' to 'product provider + third-party detection service provider', and simultaneously promoting the industrialization and marketization of molecular diagnosis and liquid biochip platform.

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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Toxicology Product Catalog

Enhancing Global Health

Toxicology Urine Test

Features and Benefits

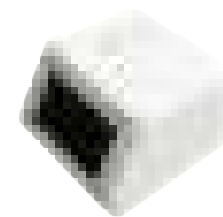
- Fast & accurate results.
- Multiple cut-off & format options.
- Convenient visual interpretation.
- Simple collection and testing procedure.
- Optional adulterant tests: CRE, GLUT, NIT, OX, pH, SG.



Strip/Cassette/Dip Card/Cup



OG-D180
Colloidal Gold Test Reader



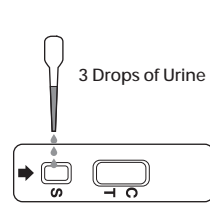
OG-D600
2 in 1 Multi-Function Colloidal Gold Test Reader

Test Procedure and Interpretation

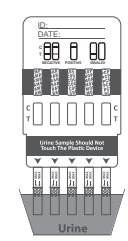
Strip Test



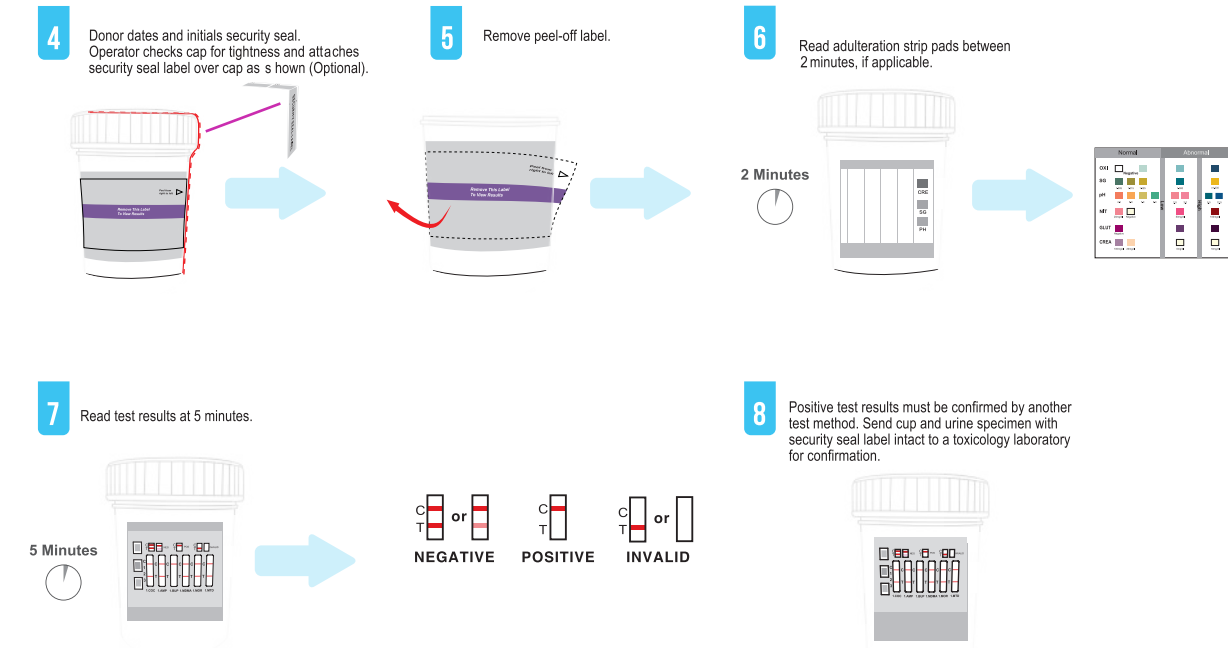
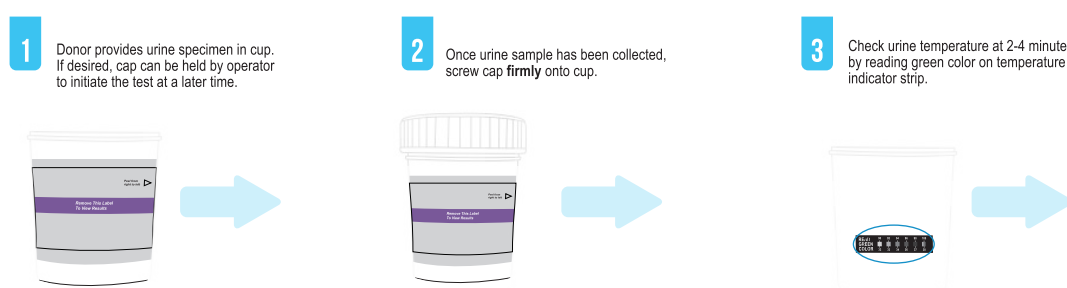
Cassette Test



Dip Card Test



Cup 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)
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)
Codine (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	600/300/200/150/50/40/25/20/18/15 ng/mL	CE 510(k)
Methadone Metabolite (EDDP) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Methamphetamine (MET) Test	Strip/Cassette/Dip Card/Cup	1000/600/300/200/50 ng/mL	CE 510(k)
Methaqualone (MQL) Test	Strip/Cassette/Dip Card/Cup	300/1000 ng/mL	CE 510(k)
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	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test

Features and Benefits

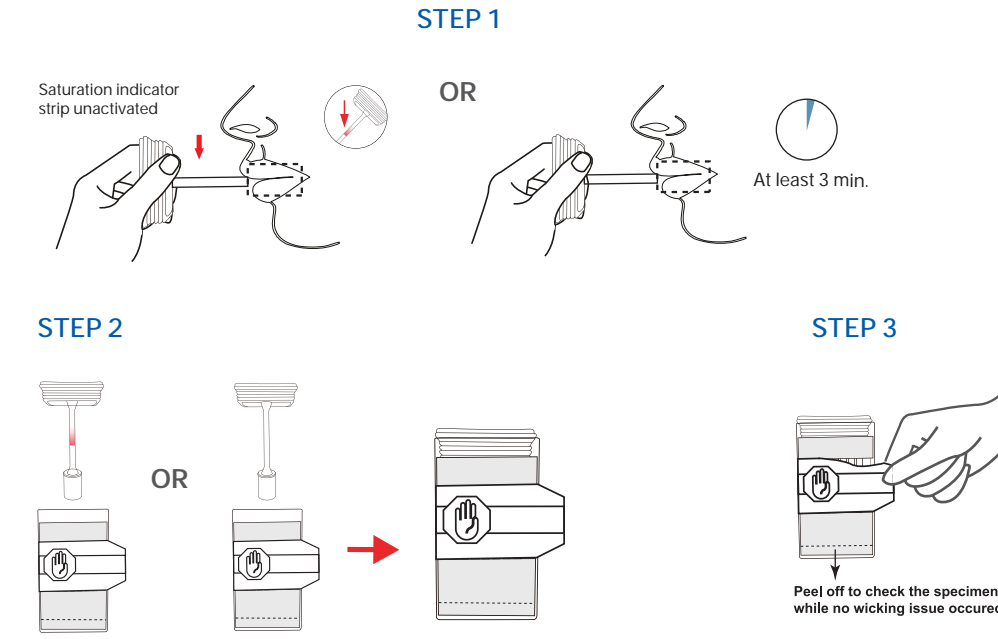
- Observed collections without privacy issues.
- Testing on-site anywhere and anytime.
- Accurate results (harder to adulterate).
- Tested for cross-reactivity against most common drugs and other substances.



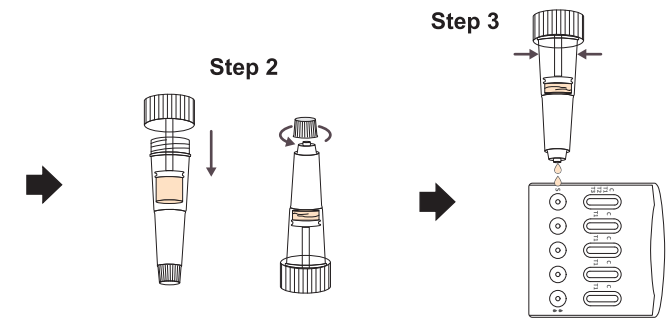
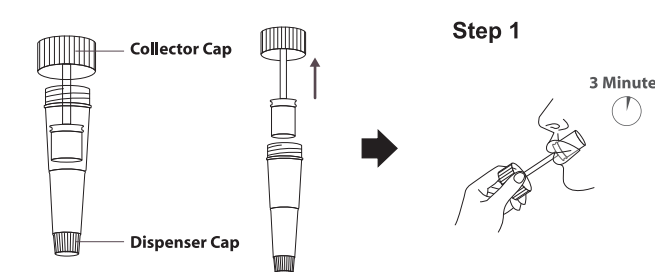
OG-D200
Handheld Oral Fluid Drug Test Reader

Test Procedure

Cube Test

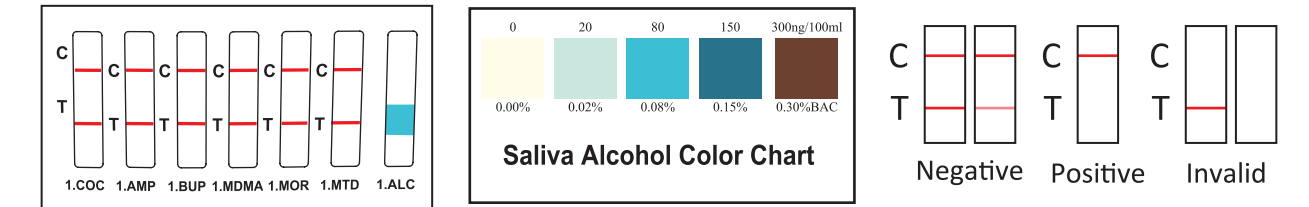


Cassette Test



Interpretation of Results

Read results at 10 minutes. If applicable, read saliva alcohol pads at 2 minutes.



Product Description	Format	Cut-off Value	Qualification
7-Aminoclozapem (ACL) Test	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
Codine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Diphenhydramine (DIP) Test	Device	150/100 ng/mL	/
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Ethyl Glucuronide (EtG) Test	Device	150/100 ng/mL	/
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydrocodone (HCD) Test	Device	10 ng/mL	/
Hydromorphone (HMO) Test	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	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 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
Phenylethylamine (PHEN) Test	Device	150/100 ng/mL	/
Pinaca Ab (K3) Test	Device	10 ng/mL	/
Pregabalin (PGB) Test	Device	100 ng/mL	/
Propoxyphene (PPX) Test	Device	50/20 ng/mL	/
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
XL-R11 Test	Device	100 ng/mL	/
Zolpidem (ZOL) Test	Device	25 ng/mL	/
Zopiclone (ZOP) Test	Device	25 ng/mL	/
Alcohol (ALC) Test	Device	0.05/0.02%	CE

One Step Multi-Drug Screen Cassette Test (Urine)

Package Insert



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

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

For healthcare professional in vitro diagnostic use only.

INTENDED USE

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

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

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

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

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

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

SUMMARY

AMPHETAMINE (AMP)

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

BARBITURATES (BAR)

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

The approximate detection time limits for Barbiturates are:

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

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

BENZODIAZEPINES (BZO)

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

BUPRENORPHINE (BUP)

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

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

COCAINE (COC)

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

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylcegonine.^{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)

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

ETHYL GLUCURONIDE (ETG)

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

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

FENTANYL (FEN)

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

KETAMINE (KET)

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

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

LYSERGIC ACID DIETHYLAMIDE (LSD)

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

MARIJUANA (THC)

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

METHADONE (MTD)

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

EDDP

EDDP is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate-dependent patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The tampering of specimens by spiking the urine with methadone can be prevented. Also, renal clearance of EDDP is not affected by urinary pH; therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone test. Methadone is an unusual drug in a sense that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure. Thus, they are very difficult to detect with immunoassays targeted to the native compound. Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance.

METHAMPHETAMINE (MET, mAMP)

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

METHAQUALONE (MQL)

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

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

METHYLENEDIOXYPYROVALERONE (MDPV)

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

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

6-MONOACETYLMORPHINE (6-MAM)

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

MORPHINE (MOP)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.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.

SYNTHETIC MARIJUANA (K2)

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

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

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

TRAMADOL (TRA)

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptor. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.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.

TRICYCLIC ANTIDEPRESSANTS (TCA)

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

ALCOHOL (ALC)

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

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

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

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

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

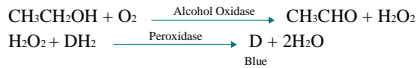
the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.

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

PRINCIPLE

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

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



REAGENTS

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

ADULTERANT TESTS (SPECIMEN VALIDITY TEST) REAGENTS

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

PRECAUTIONS

- For healthcare professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test dip card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test dip card should be discarded according to local regulations.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

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

MATERIALS

Materials Provided

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

Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

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

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



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

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

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

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

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

What Is A False Positive Test?

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

What Is A False Negative Test?

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

ALCOHOL/ADULTERANT INTERPRETATION

(Please refer to the color chart)

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

QUALITY CONTROL

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

membrane wicking and correct procedural technique.

LIMITATIONS

1. The One Step Multi-Drug Screen Cassette Test (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

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

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

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

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

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

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

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

Analytical Sensitivity

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

Analytical Specificity

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

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

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

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

Drug	Concentration (ng/mL)
MARIJUANA (THC)	
Delta-9-Tetrahydrocannabinol	50,000
11-nor-delta-9-THC-carboxyglucuronide	75
(-)-11-nor-9-carboxy-delta9-THC	75
11-Nor- Δ^9 -Tetrahydrocannabinol	50
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	5,000
11-Nor- Δ^8 -Tetrahydrocannabinol	50
Δ^8 -THC-COOH	50,000
MARIJUANA (THC 25)	
Delta-9-Tetrahydrocannabinol	25,000
11-nor-delta-9-THC-carboxyglucuronide	37.5
(-)-11-nor-9-carboxy-delta9-THC	37.5
11-Nor- Δ^9 -Tetrahydrocannabinol	25
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	2,500
11-Nor- Δ^8 -Tetrahydrocannabinol	25
Δ^8 -THC-COOH	25,000
MARIJUANA (THC 20)	
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
EDDP (Methadone Metabolites)	
EDDP	300
Disopyramide	50,000
Methadone	>100,000
EMDP	500
EDDP100 (Methadone Metabolites)	
EDDP	100
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 (MET 500)	
p-Hydroxymethamphetamine	15,000
l-Methamphetamine	4,000

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

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

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

Precision

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

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

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

REF GBD0A-1X5

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

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

Drug Conc. (Cut-off range)	COC		COC150		COT		EDDP		EDDP 100		ETG		ETG 300		FEN	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	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	41	9	44	6	42	8	50	0
Cut-off	20	30	24	26	20	30	21	29	30	20	23	27	23	27	22	28
+25% Cut-off	0	50	0	50	0	50	0	50	3	47	8	42	4	46	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)	FEN 200		FEN 100		FEN 20		K2		K2 25		KET		KET 100		MET		MET 500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	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	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	46	4	43	7	50	0	50	0	50	0	45	5	44	6	50	0	50	0
Cut-off	28	22	20	30	22	28	18	32	22	28	18	32	30	20	24	26	25	25
+25% Cut-off	5	45	2	48	0	50	0	50	0	50	6	44	3	47	0	50	0	50
+50% Cut-off	0	50	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	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	OXY		MET 300		MDMA		MOP		MQL		6-MAM		MTD		OPI	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	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	48	50	50	0	50	0	50	0
Cut-off	24	26	25	24	26	22	28	24	22	22	27	28	22	22	22	28
+25% Cut-off	0	50	0	50	0	50	0	50	6	0	5	45	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50

Drug Conc. (Cut-off range)	PCP		PPX		THC		THC 25		THC 20		TCA		TRA		LSD		MDPV	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	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	0
-50% Cut-off	50	0	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	47	3	44	6	48	2
Cut-off	22	28	26	24	20	30	23	27	25	25	22	28	25	25	21	29	24	26
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	1	49	5	45	7	43
+50% Cut-off	0	50	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	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

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

Multi-Drug Screen Cassette Test (Urine) was tested in duplicate using drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **One Step Multi-Drug Screen Cassette Test (Urine)**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

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

Non Cross-Reacting Compounds

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

BIBLIOGRAPHY

- Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.
- Ambre J. J. Anal. Toxicol. 1985; 9:241.
- Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
- Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
- FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.

INDEX OF SYMBOLS

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

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