

## 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:



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



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-245.10.07



Product Service

# EC Certificate

Full Quality Assurance System

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

**No. V1 104507 0003 Rev. 06**

**Manufacturer:**

**ACON Laboratories, Inc.**

5850 Oberlin Drive, #340  
San Diego CA 92121  
USA

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

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

**Report no.:**

SH22743EXT01

**Valid from:**

2022-05-04

**Valid until:**

2025-05-26

**Date,**

2022-05-04

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

Full Quality Assurance System

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

**No. V1 104507 0003 Rev. 06**

## Model(s):

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



# EC Certificate

Full Quality Assurance System

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

**No. V1 104507 0003 Rev. 06**

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

## Facility(ies):

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

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

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

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





**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](mailto:info@aconlabs.com)

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November 11<sup>th</sup> 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](mailto: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  
*in vitro* diagnostic device:**

*Mission*® Urinalysis Reagent Strips (U031-XX1)

**classified as Others in 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 self-declaration is according to Annex III  
(excluding Section 6) of the Directive.**

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

Signed this 11 day of February, 2020  
in San Diego, CA USA



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Qi Yi Xie, MD, MPH  
Senior Staff, Regulatory Affairs & Clinical Affairs  
Acon Laboratories, Inc.



## 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	Model Number
Mission® Liquid Urine Control	U021-011	n/a
SPINREACT Liquid Urine Control	U021-013A	n/a
Insight® Liquid Urine Control	U021-015	n/a
Mission® Liquid Diptube Urine Control	U021-071	n/a
Insight® Liquid Diptube Urine Control	U021-075	n/a

**classified as Others in 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 self-declaration is according to Annex III  
(excluding Section 6) of the Directive.**

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

Signed this 22 day of October, 2021  
in San Diego, CA, USA



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





# Certificate

No. Q5 104507 0001 Rev. 03

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

**Certification Mark:**



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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 104507 0001 Rev. 03](http://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.



# **Mission**<sup>®</sup> Urinalysis Reagent Strips and Urine Analyzers



Obtain reliable and cost-effective results with *Mission*<sup>®</sup> Urinalysis Reagent Strips and Urine Analyzers!

- **Accurate**
- **Reliable**
- **Convenient**



Global Diagnostics for Local Markets<sup>™</sup>

# Urinalysis Reagent Strips

## Simple and Accurate

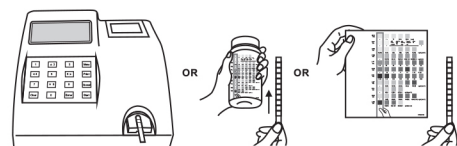
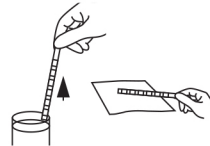
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

## Flexible

- Compatible for visual and analyzer reading
- Over 35 different combinations available

## Multiple Packaging Options and Long Shelf Life

- Canister Packaging
  - Available in 25, 50 and 100 strips per canister
  - 2 year shelf life for unopened canisters which 150 strips per kit without MA/CRE Combo offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging
  - Individually packaged strips available in kit of 3 or 6 strips for visual reading only (includes 1 color chart)
  - Unique packaging maintains 2 year shelf life for all strips in the kit compared to 3 months for remaining strips in an opened canister



Step 1: Immerse strip into urine

Step 2: Remove excess urine

Step 3: Obtain results by analyzer or visual reading

No.	Catalog No.	No. of Parameters	Type of Strip <sup>§</sup>		Reading Availability				Parameters															
			Visual Reading	Analyzer Reading	Visual	U120	U120 Ultra	U500	ASC	GLU	BIL	KET	SG	BLO	PH	PRO	URO	NIT	LEU	ALB	CRE	CA		
1	U031-141	14	14C✓		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
2	U031-131	13	13CE✓		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
3	U031-111	11	11A✓†		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
4	U031-101	10	10U✓x		Yes	Yes	Yes	Yes		*	*	*	*	*	*	*	*	*	*	*	*	*		
5	U031-191	9	9U✓x		Yes	Yes	Yes	Yes		*	*	*	*	*	*	*	*	*	*	*	*	*		
6	U031-081	8	8U✓x		Yes	Yes	Yes	Yes		*	*	*		*	*	*	*	*	*	*	*	*		
7			8N✓x		Yes	Yes	Yes	Yes		*		*	*	*	*	*		*	*	*	*	*		
8			8S✓x		Yes	Yes	No	Yes		*			*	*	*	*	*	*	*	*	*	*		
9			8K✓x		Yes	Yes	No	Yes		*	*	*		*	*	*	*	*	*	*	*	*	*	
10	U031-071	7	7N✓x		Yes	Yes	Yes	Yes		*	*	*		*	*	*	*	*	*	*	*	*		
11	U031-061	6	6N✓x	6NE✓x	Yes	Yes	No	Yes		*				*	*	*		*	*					
12			6U✓x	6UE✓x	Yes	Yes	No	Yes			*		*	*		*	*	*						
13	U031-051	5	5B✓x	5BE✓x	Yes	Yes	No	No		*		*		*	*	*								
14			5N✓x	5NE✓x	Yes	Yes	Yes	No		*				*	*	*		*	*					
15			5S✓x	5SE✓x	Yes	Yes	No	No		*			*	*	*	*								
16			5U✓x	5UE✓x	Yes	Yes	No	No			*			*	*			*	*	*				
17	U031-041	4	4P✓x	4PE✓x	Yes	Yes	Yes	Yes		*					*	*	*	*	*	*	*	*		
18			4S✓x	4SE✓x	Yes	Yes	Yes	Yes		*			*		*	*	*	*	*	*	*	*		
19			4B✓x	4BE✓x	Yes	Yes	No	No		*				*	*	*	*	*	*	*	*	*		
20			4K✓x	4KE✓x	Yes	Yes	Yes	Yes		*		*			*	*	*	*	*	*	*	*		
21			4G✓x	4GE✓x	Yes	Yes	No	No		*				*	*	*	*	*	*	*	*	*		
22			4N✓x	4NE✓x	Yes	Yes	No	Yes						*	*	*	*	*	*	*	*	*	*	
23	U031-031	3	3P✓x	3PE✓x	Yes	Yes	Yes	Yes		*				*	*	*	*	*	*	*	*	*		
24			3K✓x	3KE✓x	Yes	Yes	Yes	Yes		*		*			*	*	*	*	*	*	*	*		
25			3G✓x	3GE✓x	Yes	Yes	No	Yes		*		*		*	*	*	*	*	*	*	*	*		
26			3N✓x	3NE✓x	Yes	Yes	No	Yes						*	*	*	*	*	*	*	*	*		
27	U031-021	2	2G✓x	2GE✓x	Yes	Yes	Yes	Yes		*					*	*	*	*	*	*	*	*		
28			2K✓x	2KE✓x	Yes	Yes	Yes	Yes		*		*				*	*	*	*	*	*	*		
29			2N✓x	2NE✓x	Yes	Yes	Yes	Yes									*	*	*	*	*	*		
30			2B✓x	2BE✓x	Yes	Yes	No	Yes						*	*	*	*	*	*	*	*	*		
31			2U✓x	2UE✓x	Yes	Yes	No	Yes			*					*	*	*	*	*	*	*		
32			2S✓x	2SE✓x	Yes	Yes	No	Yes					*	*	*	*	*	*	*	*	*	*		
33			2C✓	2CE✓	Yes	Yes	Yes	Yes										*	*	*	*	*		
34			U031-011	1	1B✓x	1BE✓x	Yes	Yes	No	No					*	*	*	*	*	*	*	*	*	
35	1P✓x	1PE✓x			Yes	Yes	No	No						*	*	*	*	*	*	*	*			
36	1G✓x	1GE✓x			Yes	Yes	Yes	No		*														
37	1K✓x	1KE✓x			Yes	Yes	No	No				*												
38	1R✓x	1RE✓x			Yes	Yes	No	No							*	*	*	*	*	*	*	*		

<sup>§</sup>Type of Strip:  
 Visual Strip Size: 1-6 Parameters: 80 mm x 5 mm; 7-14 Parameters: 108 mm x 5 mm  
 U120/U500 Strip Size: 1-14 Parameters: 108 mm x 5 mm  
 \*E" means extended strip length for 1-6 Parameters and exclusive strip length for 13 Parameter  
 Default Type of Strip (U120/U500): 11A, 10U, 9U and 8N  
 Standard Black Canisters : Available for 25, 50 and 100 strips; 150 strips per kit without MA/CRE Combo  
 Pouch: Single-strip pouch available in kit of 3 or 6 for visual reading only

✓ CE Marked for sale in the European Community  
 † FDA 510(k) Cleared  
 x FDA 510(k) Cleared and CLIA Waived



# U120 Urine Analyzer



## Accurate

- Up to 120 tests/hour in Continuous Test Option
- Test categories include Routine, STAT and QC
- Automatic calibration for accurate results and easy operation

## Reliable

- Can read strips with up to 14 parameters, including Microalbumin/Creatinine/Calcium
- Minimal training required

## Convenient Operation

- Saves and recalls the last 2,000 results automatically
- Audible beep signals operator to dip strips in urine
- Can print up to 3 copies per test for convenient reviewing and easy record keeping
- Option to print results on sticker paper for quick and simple record management

## Easy Data Management

- Includes RS232C and USB ports for easy data transfer to an external computer or LIS
- Record Operator/Patient ID by Manual Entry and Barcode Reader

## Specifications

Features	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	Single Test Option: 60 tests/hour Continuous Test Option: 120 tests/hour
Test Categories	Routine, STAT and QC
Memory	Last 2,000 results
Strip Incubation Time	1 Minute
Wavelength of Monochromatic LED	525 nm and 635 nm
Default Strips	8, 9, 10, 11 Parameters (108 mm x 5 mm)
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Total Combinations Per Analyzer	4 Combinations
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer USB Port for Data Transfer 25 Pin Parallel Port for External Printer
Data Entry Capabilities	Operator/Patient ID - Manual Entry and Barcode Reader (Up to 20 characters)
Connection Capabilities	Internal Thermal Printer (included)      RS232C Barcode Reader (optional) Optional External Printer (not included)      USB or RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), EAN 8, EAN 13, Interleave 25, UPCA, UPCE
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤85% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	27.2 cm x 26.9 cm x 14.6 cm (10.7" x 10.6" x 5.7")
Display Dimensions (L x W)	10.8 cm x 5.7 cm (4.2" x 2.2")
Weight	2.6 kg (5.7 lbs) without batteries or power supply

## Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U120 Urine Analyzer	U111-101 <sup>✓X</sup>	1 Urine Analyzer 1 Strip Holder 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Quick Start Guide 1 Instruction Manual	42.0 cm x 41.5 cm x 31 cm; 5.0 kg		1
U120 Urine Analyzer with Barcode Reader	U111-111 <sup>✓X</sup>	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Quick Start Guide 1 Instruction Manual	44.5cm x 44.5cm x 40.0cm; 5.5 kg		1
Barcode Reader	U221-111 <sup>✓X</sup>	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg 9.3" x 4.3" x 3.1"; 17.0 oz	63.0 cm x 37.0 cm x 30.0 cm; 12.0 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.36kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
U120 Data Transfer Kit	U221-131 <sup>✓X</sup>	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

✓ CE Marked for sale in the European Community



X FDA 510(k) Cleared and CLIA Waived



# U120 Ultra Urine Analyzer



## Easy to Operate

- Large color touchscreen LCD for simple menu navigation
- Work List and Help Menu available for specimen review and troubleshooting
- Powered by AC adaptor or 6 AA batteries for easy portability
- Up to 2,000 patient memory and 800 Operator ID storage
- Ability to select Time Logout between 1-99 with minutes or hours option

## Accurate and Efficient

- Advanced CMOS Image Sensor ensures accurate readings
- Can read strips with up to 14 parameters, including Microalbumin, Creatinine and Calcium
- Option to edit test number sequence, or skip then return to specific test numbers
- Ability to edit abnormal results

## Simple Data Transfer

- Immediate transmission of LIS data using Bluetooth, LAN or WLAN
- Ability to update software with SD card or USB flash drive

## Unique Lockout Functions

- Strip Lockout
  - Pre-set option to prevent using strips of another brand, with a barcode reader or by manual entry
- User Lockout
  - Option to eliminate unapproved users with up to 800 operators
- QC Lockout
  - Prevents testing without passing QC
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

## Specifications

Feature	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	CMOS Image Sensor
Throughput	Single Test Option: 55 tests/hour; Continuous Test Option: 120 tests/hour
Test Modes	Quick Test Mode, Full Test Mode and Customized Test Mode
Test Category	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 Records
Strip Incubation Time	1 Minute
Wavelength	390 nm - 770 nm
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations Per Analyzer	Over 15 Combinations
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer and External Printer USB Ports for Keyboard or Data Transfer
Data Entry Capabilities	Operator ID, Patient ID/Name - Manual Entry and Barcode Reader (Up to 20 characters) Urine Color and Clarity, Strip Lot Number, and Expiration Date - Manual Entry
Connection Capabilities	Internal Thermal Printer (included) Bluetooth (included) Bluetooth Adaptor (optional) RS232C Barcode Reader (optional) USB or RS232C Data Transfer Cable (optional) SD Card or USB flash drive for Software Update (optional) Ethernet via USB to RJ45 Adaptor (optional) Keyboard (not included) Optional External Printer (not included)
Major Readable Barcodes	Code 39      EAN 8      French Pharmacode      Matrix 25      RSS Code 93      EAN 13      Industrial 25      MSI      Telepen Code 128      EAN 128      Interleave 25      Plessey      UPCA Codabar (NW-7)      Italy Pharmacode      UPCE
Screen Type	Large color touch screen LCD (12 cm x 9 cm)
LIS Interface	Formatted and compatible with HL-7 compliant, ACON standard interface, S interface, D interface, U interface and R interface for downloading of LIS data
Calibration	Automatic
Available Languages on the Screen	More than 10 languages available, including English
Analyzer Operating Conditions	0-40°C (32-104°F); 5%-85% RH
System Operating Conditions	15-30°C (59-86°F); 20%-80% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100- 240 VAC, 45-65 Hz; 6 AA Alkaline Batteries
Line Leakage Current	0.5 mA
Dimensions (L x W x H)	26 cm x 15 cm x 18 cm (10" x 6" x 7")
Display Dimensions (L x W)	12 cm x 9 cm (5" x 4")
Weight	1.7 kg (3.7 lb) without batteries or power supply

## Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U120 Ultra Urine Analyzer	U114-101 ✓	1 Urine Analyzer 2 Test Tables 2 Test Table Inserts 2 Printer Paper Rolls	1 Power Cord and Supply Adapter 1 Brush 1 Quick Start Guide 1 Instruction Manual	40 cm x 39 cm x 36 cm; 4 kg 16" x 15" x 14"; 141 oz		1
U120 Ultra Urine Analyzer with Barcode Reader	U114-111 ✓	1 Urine Analyzer 2 Test Tables 2 Test Table Inserts 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	1 Power Cord and Supply Adapter 1 Brush 1 Quick Start Guide 1 Instruction Manual	40 cm x 39 cm x 36 cm; 4 kg 16" x 15" x 14"; 141 oz		1
Barcode Reader	U124-111 ✓	1 Barcode Reader (RS232C)		23.6 cm x 10.8 cm x 7.8 cm; 0.36 kg 9.3" x 4.3" x 3.1"; 17.0 oz		22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.36 kg 4.7" x 4.7" x 2.6"; 12.7 oz 12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz 63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	50
U120 Ultra Data Transfer Kit	U124-131 ✓	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

# U500 Urine Analyzer



## Accurate and Efficient

- Up to 500 tests/hour for medium/large volume sample testing
- Professional accuracy equivalent to market leader
- Automatic strip detection and alignment for better efficiency
- Test categories include Routine, STAT and QC

## Easy to Operate

- Large touch screen LCD offers simple menu navigation
- Uniquely designed strip platform/waste tray unit for easy one-step cleaning

## Convenient

- Automatic calibration and waste disposal reduce hands-on time
- Can read strips with up to 14 parameters, including Microalbumin/Creatinine/Calcium
- Strip selection of up to 4 combinations for analyzer reading
- Stores up to 2,000 records and automatically flags abnormal results
- Capable of printing results on sticker paper for quick and easy record management

## Data Management Capability

- Includes RS232C port for easy data transfer to an external computer or LIS
- Record Operator/Patient ID by Manual Entry and Barcode Reader

## Unique Lockout Functions

- Strip Lockout
  - Pre-set option to prevent using strips of another brand, with a barcode reader or by manual entry
- User Lockout
  - Option to eliminate unapproved users with up to 10 operators
- QC Lockout
  - Prevents testing without passing QC
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

## Specifications

Feature	Specifications
Analyzer Type	Semi-Automatic
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	500 tests/hour (Measuring cycle: 7 seconds/test)
Test Categories	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 Records
Strip Incubation Time	1 Minute
Wavelength	525 and 635 nm
Default Strips	8, 9, 10, 11 Parameters (108 mm x 5 mm)
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations Per Analyzer	4 Combinations
Waste Disposal Capacity	Up to 150 Strips
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer 25 Pin Parallel Port for External Printer
Data Entry Capabilities	Operator/Patient ID - Manual Entry and Barcode Reader (Up to 25 characters)
Connection Capabilities	Internal Thermal Printer (included) RS232C Barcode Reader (optional) Optional External Printer (not included) RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), EAN 8, EAN 13, Interleave 25, UPCA, UPCE
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤85% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	36.6 cm x 28.3 cm x 19.5cm (14.4" x 11.1" x 7.7")
Display Dimensions (L x W)	11.5 cm x 9.0 cm (4.5" x 3.5")
Weight	4.0 kg (8.8 lbs) without batteries or power supply

## Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U500 Urine Analyzer	U211-101 <sup>†</sup>	1 Urine Analyzer	2 Fuses (2.0A)	51.0 cm x 42.0 cm x 38.5 cm; 7 kg	24.8" x 14.6" x 11.8"; 423.3 oz	1
		1 Strip Platform/Waste Tray	1 Power Cord			
U500 Urine Analyzer with Barcode Reader	U211-111 <sup>†</sup>	2 Printer Paper Rolls	1 Instruction Manual	20.1" X 16.5" x 15.2"; 246.9 oz	55.0 cm x 55.0 cm x 55.0cm; 9.2 kg	1
		1 Urine Analyzer	2 Fuses (2.0A)			
		1 Strip Platform/Waste Tray	1 Power Cord	21.7" x 21.7" x 21.7"; 324.5 oz		
		2 Printer Paper Rolls	1 Serial Splitter Cable (RS232C)			
		1 Barcode Reader (RS232C)	1 Instruction Manual			
Barcode Reader	U221-111 <sup>†</sup>	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg	63.0 cm x 37.0 cm x 30.0 cm; 12 kg	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll	9.3" x 4.3" x 3.1"; 17.0 oz	24.8" x 14.6" x 11.8"; 423.3 oz	50
				12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg	
				4.7" x 4.7" x 2.6"; 12.7oz	24.8" x 14.6" x 11.8"; 684.3 oz	
				12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg	
U500 Data Transfer Kit	U221-131 <sup>†</sup>	1 Data Transfer Cable (RS232C)	1 Package Insert	4.7" x 4.7" x 2.6"; 14.1oz	24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	8
				16.0 cm x 13.0 cm x 3.5 cm; 0.147kg	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg	
				6.3" x 5.1" x 1.4"; 5.2 oz	9.8" x 8.3" x 5.9"; 48.0 oz	

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† FDA 510(k) Cleared

# Urine Controls

## Reliable

- Use with *Mission®* and *Mission® Expert* Urinalysis Reagent Strips and Urine Analyzers for optimum quality control
- Validate urinalysis results and prevent procedure errors

## Quick and Convenient Testing

- Ensures accurate results for all parameters
- Obtain quick results in any setting
- Competitively priced

## Two Types of Urine Controls Available

### Liquid Urine Control

- Ready to use without dissolving in distilled water
- 24 months shelf life for unopened controls at 2-8°C
- Two Packaging Options
  - Dropper Tip Bottles
    - Dropper tip bottles provide efficient use of the control solution
    - Easily drop the control solution onto each reagent pad using the dropper tip bottle
    - Controls can be used up to 40 times within 30 days at room temperature
  - Driptubes
    - Driptube packaging allows for quick testing similar to using a urine specimen
    - Simply dip the strip into the control solution and read results
    - Controls can be used up to 20 times within 30 days at room temperature

### Dry Strip Urine Control

- Portable for use anywhere with no refrigeration required
- Dissolve the dry strip urine control in distilled water, dip urine strip in the control solution, then compare to color chart
- Each control solution can be used for up to 12 tests at 2-30°C within 8 hours for all parameters
- 24 months shelf life at 2-30°C for unopened controls

## Specifications

Features		Specifications		
Product Name		Liquid Urine Control	Liquid Driptube Urine Control	Dry Strip Urine Control
Test Parameters		LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE, CA (13)		
Solution Detection Levels	Level 1	Negative: LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE, CA		
	Level 2	Positive: LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB CRE, CA and Negative ASC		
Compatible Urine Strips		<i>Mission®</i> Urinalysis Reagent Strips, <i>Mission® Expert</i> Urinalysis Reagent Strips		
Reading Time/Stability		Refer to insert	Refer to insert	Refer to insert
Storage Temperature		2-8°C	2-8°C	2-30°C
Unopened Control Shelf Life		24 months	24 months	24 months
Opened Control Stability		30 days at 15-30°C or until the expiration date at 2-8°C	30 days at 15-30°C or until the expiration date at 2-8°C	2-30°C: 3 months for Dry Strip; 8 hours for Control Solution for all parameters
Maximum Tests per Unit		20 or 40 tests/bottle	20 tests/driptube	12 tests/control solution of 1 dry strip

## Ordering Information

Product Name	Catalog No.	Components	Kit Box Dimensions (LxWxH) & Weight	Carton Dimensions (LxWxH) & Weight	# Kits/Carton
Liquid Urine Control ✓X	U021-011	Level 1: 3 x 10 mL/bottle; Level 2: 3 x 10 mL/bottle	85 mm x 55 mm x 60 mm; 107 g	400 mm x 270 mm x 345 mm; 5.2 kg	198
		Level 1: 3 x 5 mL/bottle; Level 2: 3 x 5 mL/bottle	85 mm x 55 mm x 60 mm; 75 g	400 mm x 270 mm x 345 mm; 4.2 kg	198
		Level 1: 1 x 10 mL/bottle; Level 2: 1 x 10 mL/bottle	55 mm x 28 mm x 60 mm; 41 g	400 mm x 270 mm x 345 mm; 6.6 kg	228
		Level 1: 1 x 5 mL/bottle; Level 2: 1 x 5 mL/bottle	55 mm x 28 mm x 60 mm; 31 g	400 mm x 270 mm x 345 mm; 5.5 kg	228
Liquid Driptube Urine Control ✓X	U021-071	Level 1: 2 x 12 mL/driptube; Level 2: 2 x 12 mL/driptube	130 mm x 55 mm x 55 mm; 101 g	385 mm x 255 mm x 320 mm; 4.7 kg	30
		Level 1: 1 x 12 mL/driptube; Level 2: 1 x 12 mL/driptube	130 mm x 55 mm x 55 mm; 62 g	385 mm x 255 mm x 320 mm; 3.5 kg	30
Dry Strip Urine Control ✓X	U021-041	Level 1: 1 x 25 strips/canister; Level 2: 1 x 25 strips/canister	100 mm x 51 mm x 110 mm; 126 g	280 mm x 280 mm x 260 mm; 3.6 kg	24
		Level 1: 1 x 10 strips/canister; Level 2: 1 x 10 strips/canister	100 mm x 51 mm x 110 mm; 106 g	280 mm x 280 mm x 260 mm; 3.1 kg	24

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**We also offer other rapid diagnostic and medical products for:**

Blood Glucose Monitoring Systems, Clinical Chemistry including Urinalysis, Immunoassay EIA/ELISA and more.

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ACON Laboratories, Inc., 10125 Mesa Rim Road, San Diego, CA 92121, U.S.A. • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: [info@aconlabs.com](mailto:info@aconlabs.com)  
Please visit our website for details: [www.aconlabs.com](http://www.aconlabs.com)



# **Mission<sup>®</sup>**

## **Urine Controls**

Simply validate  
visual and analyzer  
urinalysis with  
**Mission<sup>®</sup>** Liquid and  
Dry Strip Urine  
Controls!

- *Reliable*
- *Quick and Easy*
- *Available in Liquid and Dry Strip*



Global Diagnostics for Local Markets™

# Mission® Urine Controls

## Reliable

- Use with Mission® and Mission® Expert Urinalysis Reagent Strips and Urine Analyzers for optimum quality control
- Validate urinalysis results and prevent procedure errors
- Control Level 1 provides negative results for LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB<sup>test</sup> and CRE<sup>test</sup>
- Control Level 2 provides positive results for LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB<sup>test</sup> and CRE<sup>test</sup> with negative results for ASC

## Quick and Convenient Testing

- Ensures accurate results for all parameters
- Obtain quick results in any setting
- Competitively priced

## Two Types of Urine Controls Available

### Liquid Urine Control

- Ready-to-use without dissolving in distilled water
- 24 months shelf life for unopened controls at 2-8°C
- Two Packaging Options
  - Dropper Tip Bottles-Current packaging now available in separate positive and negative levels!
    - Dropper tip bottles provide efficient use of the control solution
    - Easily drop the control solution onto each reagent pad using the dropper tip bottle
    - Control can be used up to 40 times within 30 days at room temperature
  - Diptube-New packaging available in separate positive and negative levels!
    - Diptube packaging allows for quick testing similar to using a urine specimen
    - Simply dip the strip into the control solution and read results
    - Control can be used up to 20 times within 30 days at room temperature

### Dry Strip Urine Control

- Portable for use anywhere with no refrigeration required
- Dissolve the dry strip urine control in distilled water, dip urine strip in the control solution, then compare to color chart
- Each control solution can be used for up to 12 tests at 2-30°C within 8 hours for all parameters
- 24 months shelf life at 2-30°C for unopened controls



## Specifications

Features		Specifications		
Product Name		Liquid Urine Control	Liquid Diptube Urine Control	Dry Strip Urine Control
Test Parameters		LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE (13)		
Solution Detection Levels	Level 1	Negative: LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE		
	Level 2	Positive: LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB and CRE, Negative ASC		
Compatible Urine Strips		Mission® Urinalysis Reagent Strips, Mission® Expert Urinalysis Reagent Strips		
Reading Time/Stability		Refer to insert	Refer to insert	Refer to insert
Storage Temperature		2-8°C	2-8°C	2-30°C
Unopened Control Shelf Life		24 months	24 months	24 months
Opened Control Stability		30 days at 15-30°C or until the expiration date at 2-8°C	30 days at 15-30°C or until the expiration date at 2-8°C	2-30°C: 3 months for Dry Strip; 8 hours for Control Solution for all parameters
Maximum Tests per Unit		20 or 40 tests/bottle	20 tests/diptube	12 tests/control solution of 1 dry strip

## Ordering Information

Product Name	Catalog No.	Components	Kit Box Dimensions (LxWxH) & Weight	Carton Dimensions (LxWxH) & Weight	# Kits/Carton
Liquid Urine Control <sup>†</sup>	U021-011: Combo	Level 1: 3 x 10 mL/bottle; Level 2: 3 x 10 mL/bottle	85 mm x 55 mm x 60 mm; 107 g	400 mm x 270 mm x 345 mm; 5.2 kg	198
		Level 1: 3 x 5 mL/bottle; Level 2: 3 x 5 mL/bottle	85 mm x 55 mm x 60 mm; 75 g	400 mm x 270 mm x 345 mm; 4.2 kg	198
		Level 1: 1 x 10 mL/bottle; Level 2: 1 x 10 mL/bottle	55 mm x 28 mm x 60 mm; 41 g	400 mm x 270 mm x 345 mm; 6.6 kg	228
		Level 1: 1 x 5 mL/bottle; Level 2: 1 x 5 mL/bottle	55 mm x 28 mm x 60 mm; 31 g	400 mm x 270 mm x 345 mm; 5.5 kg	228
	U021-021: Level 1; U021-031: Level 2	6 x 10 mL/bottle	85 mm x 55 mm x 60 mm; 107 g	400 mm x 270 mm x 345 mm; 5.2 kg	198
		6 x 5 mL/bottle	85 mm x 55 mm x 60 mm; 75 g	400 mm x 270 mm x 345 mm; 4.2 kg	198
		2 x 10 mL/bottle	55 mm x 28 mm x 60 mm; 41 g	400 mm x 270 mm x 345 mm; 6.6 kg	228
		2 x 5 mL/bottle	55 mm x 28 mm x 60 mm; 31 g	400 mm x 270 mm x 345 mm; 5.5 kg	228
Liquid Diptube Urine Control <sup>†</sup>	U021-071: Combo	Level 1: 2 x 12 mL/diptube; Level 2: 2 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 101 g	385 mm x 255 mm x 320 mm; 4.7 kg	30
		Level 1: 1 x 12 mL/diptube; Level 2: 1 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 62 g	385 mm x 255 mm x 320 mm; 3.5 kg	30
	U021-081: Level 1; U021-091: Level 2	4 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 101 g	385 mm x 255 mm x 320 mm; 4.7 kg	30
		2 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 62 g	385 mm x 255 mm x 320 mm; 3.5 kg	30
Dry Strip Urine Control <sup>†</sup>	U021-041: Combo	Level 1: 1 x 25 strips/canister; Level 2: 1 x 25 strips/canister	100 mm x 51 mm x 110 mm; 126 g	280 mm x 280 mm x 260 mm; 3.6 kg	24
		Level 1: 1 x 10 strips/canister; Level 2: 1 x 10 strips/canister	100 mm x 51 mm x 110 mm; 106 g	280 mm x 280 mm x 260 mm; 3.1 kg	24
	U021-051: Level 1; U021-061: Level 2	2 x 25 strips/canister	100 mm x 51 mm x 110 mm; 126 g	280 mm x 280 mm x 260 mm; 3.6 kg	24
		2 x 10 strips/canister	100 mm x 51 mm x 110 mm; 106 g	280 mm x 280 mm x 260 mm; 3.1 kg	24

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**We also offer other rapid diagnostic and medical products for:**

Blood Glucose Monitoring Systems, Clinical Chemistry including Urinalysis, Immunoassay EIA/ELISA and more.

**Contact us for worldwide distribution and custom manufacturing (OEM) opportunities**







# Certificate

No. Q5 092305 0001 Rev. 01

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

**Certification Mark:**



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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01)

**Report No.:** SH2198802

**Valid from:** 2022-04-11

**Valid until:** 2024-03-16

**Date,** 2022-04-11

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 092305 0001 Rev. 01

**Applied Standard(s):**

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

**Facility(ies):**

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

See Scope of Certificate



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

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## STATEMENT

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

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

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21



*Handwritten signature in blue ink.*

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





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



CE-DOC-OG060  
Version 1.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

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

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

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

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

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

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

We hereby explicitly appoint

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

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

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

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

Date Signed: November 28, 2017

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

# Fecal Occult Blood Rapid Test Cassette (Feces)



## INTENDED USE

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

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

## INTRODUCTION

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

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

## PRINCIPLE

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

## MATERIALS PROVIDED

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

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers      2. Clock or timer

## STORAGE AND STABILITY

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

## PRECAUTIONS

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

## PATIENT PREPARATION

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

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

## SPECIMEN COLLECTION AND PREPARATION

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

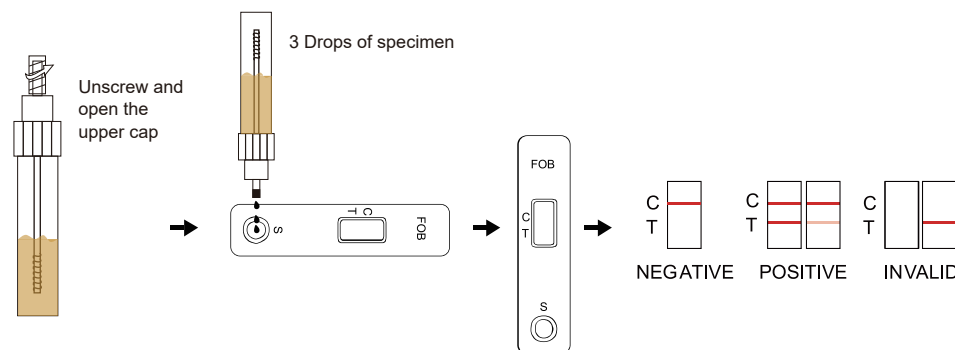
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside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

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

## TEST PROCEDURE

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

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



## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

**NOTE:**

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

# Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.

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

## QUALITY CONTROL

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

## LIMITATIONS

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

## PERFORMANCE CHARACTERISTICS

### 1. Sensitivity: 99.6%

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

### 2. Prozone Effect:

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

### 3. Specificity: 99.9%

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

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

## REFERENCES

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

## INDEX OF SYMBOLS

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

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