



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. 01

Manufacturer: ACON Laboratories, Inc.

5850 Oberlin Drive, #340 San Diego CA 92121

USA

Product Category(ies): In Vitro diagnostics for the detection of

human infections and tumor markers, blood glucose measuring self-testing systems,

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. See also notes overleaf.

Report no.: SH1974310

 Valid from:
 2019-10-24

 Valid until:
 2022-09-12

Date, 2019-10-24

Stefan Preiß

1. Pumil

Head of Certification/Notified Body

Page 1 of 4
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123



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. 01

Model(s): For Detail Models see attachment

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







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. 01

#### For the product(s)/product category (ies):

On Call Plus Blood Glucose Monitoring System,

On Call Plus Blood Glucose Test Strips,

On Call EZ II Blood Glucose Monitoring System,

On Call Redi Blood Glucose Monitoring System,

On Call Redi II Blood Glucose Test Strips,

On Call Advanced Blood Glucose Monitoring System,

On Call Advanced Blood Glucose Test Strips,

On Call Platinum Blood Glucose Monitoring System,

On Call Platinum Blood Glucose Test Strips,

On Call Chosen Blood Glucose Monitoring System,

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 Vivid Pal Blood Glucose Monitoring System (OGM-102),

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),

D-ONE Blood Glucose Monitoring System,

D-ONE Blood Glucose Test Strips,

Urinalysis Reagent Strips (Urine),

UTI Urinary Tract Infection Test Strips,

Toxoplasma IgG EIA Test Kit,

Toxoplasma IgM EIA Test Kit,

Rubella IgG EIA Test Kit,

Rubella IgM EIA Test Kit,

CMV IgG EIA Test Kit,

Page 3 of 4

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(List A and B and devices for self-testing)

#### No. V1 104507 0003 Rev. 01

CMV IgM EIA Test Kit,

Total PSA EIA Test Kit,

PT Coagulation Monitoring System (CCM-121),

PT Coagulation Test Strips (CCS-121),

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)

On Call GU Dual Blood Glucose & Uric Acid Monitoring 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** 







#### **STATEMENT**

We, ACON Laboratories, Inc. having a registered office at 5850 Oberlin Drive #340, San Diego, CA 92121 assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EC.

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 authorization will be valid for one year after the date of this statement.

Date: June 1, 2021

Signature:

Qiyi Xie, Md, MPH

Sr. Officer, Regulatory & Clinical Affairs

ACON Laboratories, Inc.

Ph: 858-875-8011

Email: gxie@aconlabs.com







## Certificate

Certification Mark:

No. Q5 104507 0001 Rev. 01

Holder of Certificate: ACON Laboratories, Inc.

5850 Oberlin Drive, #340 San Diego CA 92121 USA

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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). See also notes overleaf.

Report No.: SH1974310

 Valid from:
 2019-10-24

 Valid until:
 2022-09-06

Date, 2019-10-24

Stefan Preiß

Head of Certification/Notified Body





## Certificate

No. Q5 104507 0001 Rev. 01

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

ACON Laboratories, Inc. Facility(ies):

5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.

10125 Mesa Rim Road, San Diego CA 92121, USA

ACON Laboratories, Inc.

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

AZURE Institute, Inc.

10125 Mesa Rim Road, San Diego CA 92121, USA



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

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

Jassy Alvarenga

International Account Manager

ACON Laboratories, Incs.A.

jalvarenga@aconlabs.com

+1 858 875 8085

# Mission® Urinalysis Reagent Strips and Urine Analyzers



# **Urinalysis Reagent Strips**

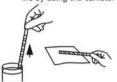
#### Simple and Accurate

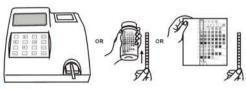
- Analytical sensitivity better than or comparable to market leaders
- · High quality color chart ensures accurate visual reading

- · Compatible for visual and analyzer reading
- · More than 30 different combinations available

#### Multiple Packaging Options and Long Shelf Life

- Canister Packaging
   Available in 25, 50, 100 and 150 strips per kit
  - · 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
- 3 month shelf life for strips in opened canisters Pouch Packaging New!
- · Single-strip Pouch
  - Individually packaged strips with 1, 3, 6 and 20 strips and 1 color chart per kit for OTC or low volume testing
- . Unique packaging maintains 2 year shelf life for all strips in the kit compared to 3 months for remaining strips in an opened canister
- Multi-strip Pouch
- · Canister Refill Kits with 25 strips/pouch uniquely packaged to save cost for low volume testing and extended shelf life by using the canister for refills





Step 1: Immerse strip into urine				Step 2: I	Remov	e exce	ss uri	ne S	Step 3: Obtain results by analyzer or visual reading																		
Catalon	No of	Type of Strip *		Reading Method Analyzer-Read			Analyzer-Read	Parameters																			
Catalog No.	No. of Parameters	For Visual Reading	For Analyzer Reading (U120/U500)	Strips per Canister	Pouch Packaging*	Visual	U120	U500	Strips: Standard (S) or Additional (A)	ASC	GLU	BIL	KET	sg	BLO	рН	PRO	URO	NIT	LEU	ALB	CRE					
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12-13 Parameters: 5 mm x 121 mm U120/U500 Strip Size

1-11 Parameters: 5 mm x 108 mm; "E" means extended strip length for 1-6 Parameters

- Visual Strip Size 1-6 Parameters: 5 mm x 80 mm; 7-11 Parameters: 5 mm x 108 mm;
  - Not available in canisters of 150 strips
    - ▲ Single-strip Pouch available in 1,3, 6 and 20 strip kit
      Canister Refill Kit, with 25 strips per pouch or canister, available in 3-pouch and 1- canister kit, or 4-pouch kit



Also available in canisters of 25, 50 and 150 strips

# **U120 Urine Analyzer**



- Accurate

   Up to 120 tests/hour in Continuous Test Option
- · Capable of reading 1 strip at a time in Single Test Option
- · Test modes include Routine, STAT and QC
- · Automatic calibration for accurate results and easy operation

- Can read up to 4 Strip combinations with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request

- 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 port for easy data transfer to an external computer or LIS
   Optional Barcode Reader to record patient ID

#### Unique Lockout Functions new!

- Strip Lockout
  - Prevents using strips of another brand on the U120 Urine Analyzer
  - · Requires barcode reader scan or manual entry of the canister code
- User Lockout

  - Eliminates unapproved users from testing
     Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings
- QC Lockout
  - · Prevents testing without passing QC
  - Prevents testing without passing 4C
     QC tests can be performed once every 8 hours, day, week or month
     Analyzer will alert when to run QC test

  - . If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

#### Specifications

Feature	<b>Specifications</b>						
Analyzer Type	Manual						
Methodology	Reflectance Photometry						
Detection	Photosensitive Diode						
Throughput	Single Test Option: 60 tests/hour Continuous Test Option: 120 tests/hour						
Test Modes	Routine, STAT and QC						
Lockout Functions	Strip Lockout: Available Upon Request; Us	er/QC Lockout: Included with option to turn ON/OF					
Memory	Last 2,000 results	**					
Strip Incubation Time	1 Minute						
Wavelength of Monochromatic LED	525 nm and 635 nm						
Standard Strips	8, 9, 10, 11 Parameters (5 mm x 108 mm	n)					
Additional Strips Available	1-11 Parameters (5 mm x 108 mm); see U	RS Parameters					
Total Combinations Per Analyzer	4 Combinations						
Analyzer Ports	Standard RS232C Port for Barcode Reader or Data Transfer USB Port for Data Transfer 25 Pin Parallel Port for External Printer						
Capabilities	Internal Thermal Printer (included) Optional External Printer (not included)	RS232C Barcode Reader (optional) USB or RS232C Data Transfer Cable (optional)					
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), Inte EAN 8, EAN 13	rleaved 25, UPC-A, UPC-E,					
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	1.6" 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)						

#### **Ordering Information**

Product Name Catalog No.		Co	mponents		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>†</sup>	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls		2 Fuses (2.0A) 1 Power Cord	42.0 cm x 41.5 cm x 3	1			
0 120 Offile Arialyze	U111-101*1			1 Quick Start Guide 1 Instruction Manual	16.4" x 16.2" x 12.				
U120 Urine Analyzer	U111-111√ <sup>†</sup>	1 Urine Analyzer 1 Strip holder		2 Fuses (2.0A) 1 Power Cord	44.5cm x 44.5cm x 4				
with Barcode Reader	Omin	2 Printer Paper Roll 1 Barcode Reader (	i Quick Start Guide		17.5" x 17.5" x 15.7"; 194 oz				
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; 12.0 kg 9.3" x 4.3" x 3.1"; 17.0 oz 24.8" x 14.6" x 11.8"; 423.3 oz		22		
Printer Paper Rolls	11404 404	J121-101 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		
	0121-101				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; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz			
U120 Data Transfer Kit	Data Transfer Kit U221-131 <sup>à</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			

# **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 modes 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 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request

Strip selection of up to 4 combinations for analyzer reading

Stories 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 R\$232C port for easy data transfer to an external computer or LIS
Optional Barcode Reader to record patient ID
Unique Lockout Functions Coming Soon!

Strip Lockout
 Prevents using strips of another brand on the U500 Urine Analyzer
 Requires barcode reader scan or manual entry of the canister code

User Lockout

Eliminates unapproved users from testing
 Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings.

QC Lockout
 Prevents testing without passing QC

QC tests can be performed once every 8 hours, day, week or month
 Analyzer will alert when to run QC test

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 secon	ids/test)				
Test Modes	Routine, STAT and QC	atriana (monomora )				
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					
Standard Strips	8, 9, 10, 11 Parameters (5 mm x 108 mm)	)				
Additional Strips Available	1-11 Parameters (5 mm x 108 mm); see URS	Parameters				
Total Combinations Per Analyzer	4 Combinations					
Waste Disposal Capacity	Up to 150 Strips					
Analyzer Ports	Standard RS232C Port for Barcode Read 25 Pin Parallel Port for External Printer	ler or Data Transfer				
Capabilities	Internal Thermal Printer (included) Optional External Printer (not included)	RS232C Barcode Reader (optional) RS232C Data Transfer Cable (optional)				
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), Interle	eaved 25, UPC-A, UPC-E, EAN 8, EAN 13				
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 19.5 cm (14.4" x 11.1"	" x 7.7")				
Display Dimensions (LxW)	11.5 cm x 9.0 cm (4.5" x 3.5")	Africa				
Weight	4.0 kg (8.8 lbs)					

#### **Ordering Information**

Product Name	e Catalog No. Components				Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton		
transaction recommendation of the s	112	1 Urine Analyzer 1 Strip Platform/Waste Tray		2 Fuses (2.0A) 1 Power Cord	51.0 cm x 42.0 cm x 3				
U500 Urine Analyzer	U211-101√	2 Printer Paper Rolls			20.1" X 16.5" x 15.2"; 246.9 oz				
U500 Urine Analyzer	U211-111√	1 Urine Analyzer 1 Strip Platform/Waste	e Tray	2 Fuses (2.0A) 1 Power Cord	55.0 cm x 55.0 cm x	55.0cm; 9.2 kg	1		
with Barcode Reader	02111111	[		Serial Splitter Cable (RS232C)     Instruction Manual	21.7" x 21.7" x 21.7"; 324.5 oz				
Barcode Reader	U221-111à	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 9.3" x 4.3" x 3.1"; 17.0 oz 24.8" x 14.6" x 11.8"; 423.3 oz		22		
Printer Paper Rolls	LIADA ADA	U121-101 4 Printer Paper Rolls -	Thermal Paper (0.06 m x 20 m): 200 results/roll		12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg 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		
	0121-101			per (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg 4.7" x 4.7" x 2.6"; 14.10z				
U500 Data Transfer Kit	U221-131√	1 Data Transfer Cable	(RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147kg 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		

#### We also offer other rapid diagnostic and medical products:

Blood Glucose Monitoring Systems, Immunoassay EIA/ELISA and more.

✓ CE Marked for sale in the European Community † Cleared for US 510(k)



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