





# **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. 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: Valid until: 2019-10-24 2022-09-12

Date,

2019-10-24

1. Pumil

Stefan Preiß Head of Certification/Notified Body

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





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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





# **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. 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,

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# **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. 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** 

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# Certificate No. Q5 104507 0001 Rev. 01

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). See also notes overleaf.

Report No.:

SH1974310

Valid from: Valid until: 2019-10-24 2022-09-06

Date,

2019-10-24

1. Pumil

Stefan Preiß Head of Certification/Notified Body





# Certificate No. Q5 104507 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): ACON Laboratories, Inc. 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

# **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 ® U500 Urine Analyzer (U211-101, U211-111)

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<sup>th</sup> day of December, 2019 in San Diego, CA, USA

Qiyi Xie, MD, MPH Senior Staff, Regulatory Affairs & Clinical Affairs 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 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



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, Cerbari Oleg, 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, Inc jalvarenga@aconlabs.com +1 858 875 8085

# **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			
		· · · · · · · · · · · · · · · · · · ·		Urine Analyzer 2 Fuses (2.0A) Strip Platform/Waste Tray 1 Power Cord		51.0 cm x 42.0 cm x 38.5 cm; 7 kg				
U500 Urine Analyzer	U211-101 <sup>à</sup>	2 Printer Paper Roll		1 Instruction Manual	20.1" X 16.5" x 15.	20.1" X 16.5" x 15.2"; 246.9 oz				
U500 Urine Analyzer	U211-111√ <sup>†</sup>	,		2 Fuses (2.0A) 1 Power Cord	55.0 cm x 55.0 cm x 5	55.0cm; 9.2 kg	1			
with Barcode Reader	Reader         0211111         2 Printer Paper Rolls           1 Barcode Reader (RS232C)			1 Serial Splitter Cable (RS232C) 1 Instruction Manual	21.7" x 21.7" x 21.					
Barcode Reader	U221-111 <sup>à</sup>	1 Barcode Reader (I	RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x10.8 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 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22			
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal F	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			
			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"; 14.1oz	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					
U500 Data Transfer Kit	U221-131 <sup>à</sup>	1 Data Transfer Cable	e (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			



# **Mission® 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



# **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
- · More than 30 different combinations available

### Multiple Packaging Options and Long Shelf Life

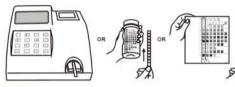
- Canister Packaging
   Available in 25, 50, 100 and 150 strips per kit
- · 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
- · 3 month shelf life for strips in opened canisters
- Pouch Packaging New!
- Single-strip Pouch
  - Individually packaged 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: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

		Type of Strip *				Reading Method Analy		Analyzer-Read	Parameters																	
Catalog No.	No. of Parameters	For Visual	For Analyzer Reading (U120/U500)	Strips per Canister *	Pouci	per Pouch ter <sup>♦</sup> Packaging <sup>▲</sup>	Strips: Standard (S)			ASC GLU BIL KET SG BLO PH PRO URO NIT LEU ALB CRE																
NO.	ranameters	For Visual Reading	(U120/U500)	Carnister	rackaging	Visual	U120	U500	or Additional (A)	ASC	GLU	BIL	KET	SG	BLO	рН	PRO	URO	NIT	LEU	ALB	CRE				
U031-131	13	13C	NA	100*	~	1	NA	NA	A	*	*	*	*	*	*	*	*	*	*	*	*	*				
U031-111	11		I1A	100	~	1	1	1	S	*	*	*	*	*	*	*	*	*	*	*						
		12	10U	100		1	~	1	S		*	*	*	*	*	*	*	*	*	*						
U031-101	10		10A	100	~	~	1	~	А	*	*	*	*	*	*	*	*	*	*							
			10C	100*		1	~	1	S		*		*	*	*	*	*		*	*	*	*				
U031-091	9		90	100	✓	~	1	~	S		*	*	*	*	*	*	*	*	*							
			BU			1	~	1	Α		*	*	*		*	*	*	*	*							
U031-081	8		BN	100	4	~	1	1	S		*		*	*	*	*	*		*	*						
		-	BS			1	1	1	A		*		1	*	*	*	*	*	*	*						
U031-071	7		7N	100	~	1	1	1	A		*		*		*	*	*	_	*	*						
U031-061	6	6N	6NE	100	1	~	~	~	A		*				*	*	*		*	*						
		6U	6UE			1	1	1				*	1	*	*		*	*	*							
		5B	5BE			1	1				*		*		*	*	*									
U031-051	5	5N	5NE	100	×	1	1	~	A		*			_	*		*	_	*	*						
94505/1, "6:601	(3) (3)	5S	5SE	0.5875576		1	~				*			*	*	*	*									
		5U	5UE			1	~					*	_	-	*		-	*	*	*						
		4S	4SE			1	1	~			*		0	*		*	*	_								
		4B	4BE				~				*				*	*	*									
U031-041	4	4K	4KE	100	100	100	100			0 1	1	1	A		*		*			*	*					
		4G	4GE					1	1		1.11		*				*		*			*				
		4N	4NE					1	1	*							*		*		*	*				
		4P	4PE			4	1	1			*		Ú.				*		*	*						
		3P	3PE			1	~	~			*					*	*									
U031-031	3	ЗK	3KE	100	~	× ×	~	1	А		*		*				*									
		3G	3GE		· ·		1	1			*		*			*										
		ЗN	3NE			1	1	1						-	*				*	*						
		2G	2GE			4	1	~			*						*									
		2K	2KE			1	~	1			*		*													
10000000000000	100	2N	2NE			1	$\checkmark$	1							*					*						
U031-021	2	2B	2BE	100	1	1	~	1	A		*		*													
		2U	2UE			1	1	1											*	*						
		2S	2SE			1	~	1						*		*										
		2C	2CE	100*		4	1	1									_				*	*				
		1B	1BE			1	1				_		_		*		-									
		1P	1PE			1	~	1			-			_		*	-				,					
U031-011	1	1G	1GE	100	×	1	~	~	A		*															
		1K	1KE			1	~	1					*													
		1R	1RE			× ×	1									*										

♦Type of Strip:

Visual Strip Size

1-6 Parameters: 5 mm x 80 mm; 7-11 Parameters: 5 mm x 108 mm; 12-13 Parameters: 5 mm x 121 mm U120/U500 Strip Size

Also available in canisters of 25, 50 and 150 strips 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

1-11 Parameters: 5 mm x 108 mm:

"E" means extended strip length for 1-6 Parameters

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

F

# **U120 Urine Analyzer**





- 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

## Reliable

 Can read up to 4 Strip combinations with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request · 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 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 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	Specif	Specifications					
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/OFF					
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	.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.			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>à</sup>		1 Urine Analyzer 1 Strip holder		2 Fuses (2.0A) 1 Power Cord	42.0 cm x 41.5 cm x 3	31		
		2 Printer Paper Rolls		1 Quick Start Guide 1 Instruction Manual	16.4" x 16.2" x 12.			
U120 Urine Analyzer U111-111à		1 Urine Analyzer 1 Strip holder		2 Fuses (2.0A) 1 Power Cord	44.5cm x 44.5cm x 4	0.0cm; 5.5 kg		
with Barcode Reader	San an	2 Printer Paper Roll 1 Barcode Reader (		1 Serial Splitter Cable (RS232C) 1 Quick Start Guide 1 Instruction Manual	17.5" x 17.5" x 15.	3		
Barcode Reader	U221-111à	1 Barcode Reader (I	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			Thermal P	Paper (0.06 m x 20 m): 200 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	
r finter r aper Rona	U121-101	4 Thinker Tuper Rono	Sticker Pa	aper (0.06 m x 9 m): 100 results/roll	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	2.20	
U120 Data Transfer Kit	U221-131 <sup>à</sup>	1 Data Transfer Cable	e (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 buch screen LCD offers simple menu navigation
 Uniquely designed strip platform/waste tray unit for easy one-step cleaning

### Convenient

- 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 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 Optional Barcode Reader to record patient ID Unique Lockout Functions <sup>Coming Scont</sup>

- 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 seco	nds/test)				
Test Modes	Routine, STAT and QC					
Lockout Functions	Strip Lockout: Available Upon Request; Use	r/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 Rea 25 Pin Parallel Port for External Printer	der 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), Inter	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 (L x W)	11.5 cm x 9.0 cm (4.5" x 3.5")					
Weight	4.0 kg (8.8 lbs)					

## **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			
		1 Urine Analyzer 1 Strip Platform/Waste Tray				51.0 cm x 42.0 cm x 38.5 cm; 7 kg				
U500 Urine Analyzer	U211-101	2 Printer Paper Roll		1 Instruction Manual	20.1" X 16.5" x 15.	1				
1122221137 / Z C		1 Urine Analyzer		2 Fuses (2.0A)	55.0cm; 9.2 kg					
U500 Urine Analyzer with Barcode Reader	U211-111√	1 Strip Platform/Wast 2 Printer Paper Roll 1 Barcode Reader (I	s	1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Instruction Manual	21.7" x 21.7" x 21.7"; 324.5 oz		1			
Barcode Reader	U221-111à	1 Barcode Reader (I	RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x10.8 cm x 7.8 cm; 0.482 kg 63.0 cm x 37.0 cm x 30.0 cm; 12 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			Thermal F	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"; 12.7 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	g			
Finiter Paper Rolls	U121-101	4 Finter Paper Rolls	Sticker Pa	aper (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"; 14.1oz	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	1.000			
U500 Data Transfer Kit	U221-131√	1 Data Transfer Cable	e (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:

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