



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. 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
Head of Certification/Notified Body

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 (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

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(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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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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

- 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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Product Service

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

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

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Product Service



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

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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:

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

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

Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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



ACON®

Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

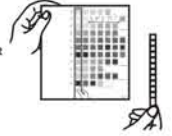
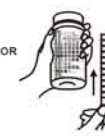
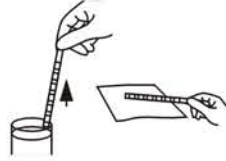
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

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

Catalog No.	No. of Parameters	Type of Strip [♦]		Strips per Canister [◇]	Pouch Packaging [▲]	Reading Method			Analyzer-Read Strips: Standard (S) or Additional (A)	Parameters														
		For Visual Reading	For Analyzer Reading (U120/U500)			Visual	U120	U500		ASC	GLU	BIL	KET	SG	BLO	pH	PRO	URO	NIT	LEU	ALB	CRE		
U031-131	13	13C	NA	100*	✓	✓	NA	NA	A	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-111	11		11A	100	✓	✓	✓	✓	S	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-101	10		10U	100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*	*	*	
			10A			✓	✓	✓	A	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
			10C			✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-091	9		9U	100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-081	8		8U	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
			8N			✓	✓	✓	S	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
			8S			✓	✓	✓	A	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-071	7		7N	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-061	6	6N	6NE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
		6U	6UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-051	5	5B	5BE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
		5N	5NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	
		5S	5SE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*
		5U	5UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-041	4	4S	4SE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
		4B	4BE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	
		4K	4KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*
		4G	4GE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*
		4N	4NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*
		4P	4PE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-031	3	3P	3PE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
		3K	3KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
		3G	3GE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
		3N	3NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
U031-021	2	2G	2GE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
		2K	2KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
		2N	2NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
		2B	2BE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
		2U	2UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
		2S	2SE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
		2C	2CE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*		
U031-011	1	1B	1BE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*	
		1P	1PE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*			
		1G	1GE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*			
		1K	1KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*			
		1R	1RE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*			

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

◇ 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



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

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	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; User/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)
Additional Strips Available	1-11 Parameters (5 mm x 108 mm); see URS 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) 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), Interleaved 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)	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.	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 [†]	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 16.4" x 16.2" x 12.1"; 176.4 oz		1
U120 Urine Analyzer with Barcode Reader	U111-111 [†]	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	44.5 cm x 44.5 cm x 40.0 cm; 5.5 kg 17.5" x 17.5" x 15.7"; 194 oz		1
Barcode Reader	U221-111 [†]	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; 0.36 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	50
U120 Data Transfer Kit	U221-131 [†]	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147 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 **CE**
 † Cleared for US 510(k)

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
- 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 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 seconds/test)
Test Modes	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
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 Reader or Data Transfer 25 Pin Parallel Port for External Printer
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), Interleaved 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 19.5cm (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)

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 [✓]	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual	51.0 cm x 42.0 cm x 38.5 cm; 7 kg 20.1" X 16.5" x 15.2"; 246.9 oz	1
U500 Urine Analyzer with Barcode Reader	U211-111 [✓]	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Instruction Manual	55.0 cm x 55.0 cm x 55.0cm; 9.2 kg 21.7" x 21.7" x 21.7"; 324.5 oz	1
Barcode Reader	U221-111 ^{✓†}	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	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; 0.360 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 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	50
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	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 **CE**

† Cleared for US 510(k)



Mission[®] Hb Hemoglobin Testing System



Accurately detects Hb and Hct levels with the *Mission[®]* Hb Hemoglobin Testing System!

- *Quick*
- *Reliable*
- *Portable*
- *Convenient*



Global Diagnostics for Local Markets[™]

Hb Hemoglobin Testing System



Quick

- Hemoglobin (Hb) and Hematocrit (Hct) results in < 15 seconds
- Simply insert strip, apply specimen and read results
- Features auto-calibration for added convenience
- No specimen preparation required
- Low maintenance and quick clean up

Accurate

- Only a single drop of fingertip blood or 10 µL capillary blood required
- Precise results equivalent to automatic hematology analyzers
- Wide Hb measurement range of 5-25.6 g/dL with Hct range of 15-75%
- Stores up to 1,000 result

Portable

- Operated by battery or optional AC adaptor
- Small and handheld for immediate diagnosis
- Ready to use in any point of care setting
- Dry strips eliminate inconvenience in shipping and storage of liquid reagents

Convenient

- Can test capillary and venous whole blood
- Minimal training required
- Easy to read large LCD
- Quick data transfer via USB port

Specifications

Feature	Technical Specification
Methodology	Reflectance Photometry
Detection Principle	Methemoglobin
Time to Results	< 15 seconds
Memory	1,000 tests with date/time and ID number
Specimen Volume	10 µL
Specimen Type	Capillary and Venous whole blood
Hb Measurement Range	5-25.6 g/dL
Hct Range	15-75%
Wavelengths	525 nm
PC Interface	USB Port
Calibration	Automatic
Hb Within Run Precision CV	≤ 3%
Hb Total Precision CV	≤ 3%
Accuracy	Hb 5-10 g/dL, ± 0.4 g/dL; Hb 10-25.6g/dL, ± 4%
Ambient Operating Conditions	10-40 °C (50-104 °F); ≤ 85% RH
Optimum Operating Conditions	15-30 °C (59-86 °F); ≤ 85% RH
Meter Storage Conditions	0-50 °C (32-122 °F); ≤ 90% RH
Strip Storage Conditions	2-30 °C (36-86 °F); ≤ 85% RH
Strip Shelf Life	2 years unopened canister; 3 months opened canister
Power Source	3 AAA Batteries or AC Adaptor
Battery Life	2,700 tests or 360 hours
Automatic Shut Off	8 minutes
Line Leakage Current	3 µA
Meter Dimensions (L X W X H)	127 mm x 58 mm x 25 mm (5.0" x 2.28" x 0.09")
LCD Dimensions (L X W)	39 mm x 37 mm (1.54" x 1.46")

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
Hb Hemoglobin Testing System	C111-3011 ✓	1 Meter 3 Batteries 1 Manual 25 Test Strips 1 Carrying Case 1 Quick Reference Guide 1 Code Chip 1 Strip Insert 1 Warranty Card	130 mm x 70 mm x 180 mm (5.12" x 2.76" x 7.08"); 270 g (9.5 oz.)	465 mm x 425 mm x 235 mm (5.12" x 2.76" x 7.08"); 7.76 kg (17.1 lbs.)	15
	C111-3021 ✓	1 Meter 10 Lancets 3 Batteries 1 Manual 10 Test Strips 1 Lancing device 1 Carrying Case 1 Quick Reference Guide 1 Code Chip 2 Control Strips 1 Strip Insert 1 Warranty Card			
Hb Hemoglobin Test Strips	C131-3011 ✓	50 Test Strips 1 Code chip 1 Strip Insert	68 mm x 40 mm x 80 mm; 54 g	435 mm x 225 mm x 370 mm (22" x 17" x 7.5"); 6 kg (13.2 lbs.)	120
		100 Test Strips 1 Code chip 1 Strip Insert	136 mm x 40 mm x 80 mm; 108 g		60
Hb Hemoglobin Adaptor Kit	C121-3011 ✓	1 Power Adaptor	8 mm x 130 mm x 70 mm (3.46" x 2.16" x 3.54"); 75 g (2.65 oz.)	375 mm x 300 mm x 400 mm (14.76" x 11.81" x 15.75"); 7.5 kg (16.5 lbs.)	80
Hb Hemoglobin Data Transfer Kit	C121-3021 ✓	1 USB Cable 1 Installation Disk	160 mm x 130 mm x 35 mm (6.3" x 5.1" x 1.4"); 120 g (4.23 oz.)	250 mm x 210 mm x 150 mm (9.84" x 8.72" x 5.9"); 1.3 kg (2.87 lbs.)	8

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

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