



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

## Declaration of Conformity

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

**We, the manufacturer, declare under our sole responsibility that the  
in vitro diagnostic device:**

Device Name	REF Number
On Call® Plus Blood Glucose Monitoring System	G113-111
On Call® Plus Blood Glucose Meter	G113-211, G113-214
On Call® Plus Blood Glucose Test Strips	G133-111, G133-112, G133-114, G133-115, G133-117, G133-118, G133-119, G133-211
On Call® Plus Glucose Control Solution	G123-311

**classified for *Annex II List B* of the directive 98/79/EC,  
meets all the provisions of the directive 98/79/EC on *in vitro*  
diagnostic medical devices which apply to it**

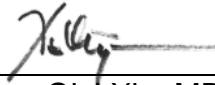
**The declaration according to Annex IV of the Directive  
is based on approval by the notified body  
TÜV SÜD Product Service GmbH,  
Ridlerstraße 65,  
80339 MÜNCHEN, Germany,  
notified under No. 0123 to the EC Commission**

This declaration is valid until expiration of EC Certificate  
No. V1 104507 0003 Rev. 06  
Expiration Date: 2025-05-26

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



Signed this 25 day of May, 2022  
in San Diego, CA USA



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



5850 Oberlin Drive #340-San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099  
E-mail: [info@aconlabs.com](mailto:info@aconlabs.com)

## 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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Qiyi 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 medical device:**

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

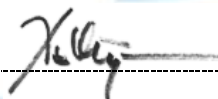
**of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,  
meets all the provisions of the directive 93/42/EEC as amended by directive  
2007/47/EC concerning medical devices which apply to it.**

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

This declaration is valid until expiration of EC Certificate  
No. G1 104507 0002 Rev. 01  
Expiration Date: 2023-09-06

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

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



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



## 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)





# 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.



## Specification

Feature	Specification
Technology	Biosensor/Electrochemical, Glucose oxidase (GOD)
Result Calibration	Plasma-equivalent
Test Time	10 seconds
Sample Size	0.5 µL
Sample Type	Fresh capillary whole blood
Hematocrit Range	25 - 60%
Glucose Test Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Memory Storage	300 results with date and time
Test Averaging	7, 14, 30-day averages
Data Transfer	USB
Control Solution	3 levels
Audio Feature	Optional beep for sample detection, error messages
Automatic Shutoff	2 minutes after last action
Battery	One (1) CR 2032 3.0V coin cell battery
Battery Life	1,000 measurements
Operating Conditions	41 - 113 °F (5 - 45°C) and 10 - 90% relative humidity
Strip Storage Temperature	2-35°C
Expiration Date	24 months (6 months after first opening)

## Catalog

Product Name	Catalog No.	Contents			
On-Call® Plus Blood Glucose Monitoring System	G113-111 v †	1 Meter 1 Manual 10 Lancets	10 Test Strips 1 Carrying Case 1 Code Chip	1 Control Solution 1 1 Quick Reference Guide 1 Clear Cap (for testing on forearm and palm)	1 Lancing Device 1 Warranty Card
On-Call® Plus Blood Glucose Meter	G113-211 v †	1 Meter 1 Manual	1 Control Solution 1 1 Warranty Card	1 Carrying Case 1 Quick Reference Guide	
	G113-214 v	1 Meter 1 Manual 10 Lancets	1 Lancing Device 1 Carrying Case 1 Warranty Card	1 Control Solution 1 1 Quick Reference Guide 1 Clear Cap (for testing on forearm and palm)	
On-Call® Plus Blood Glucose Test Strips	G133-111 v †	50 Test Strips (25/vial)	1 Code Chip	1 Package Insert	
	G133-112 v	50 Test Strips (50/vial)	1 Code Chip	1 Package Insert	
	G133-114 v	100 Test Strips (25/vial)	1 Code Chip	1 Package Insert	
	G133-115 v	10 Test Strips (10/vial)	1 Code Chip	1 Package Insert	
	G133-117 v	25 Test Strips (Individually Foil Wrapped)	1 Code Chip	1 Package Insert	
	G133-118 v	50 Test Strips (Individually Foil Wrapped)	1 Code Chip	1 Package Insert	
	G133-118 v	25 Test Strips (25/vial)	1 Code Chip	1 Package Insert	
On-Call® Plus Blood Glucose Test Strips and Lancets	G133-211 v	50 Test Strips (25/vial)	50 Lancets (25/bag)	1 Code Chip	1 Package Insert
On-Call® Plus Blood Glucose Control Solution	G123-311 v†	1 Control Solution 0	1 Control Solution 1	1 Control Solution 2	1 Package Insert
On-Call® Lancets	G124-10A v†	100 Lancets (25/bag)			
On-Call® Lancing Device	G124-11AV	1 Lancing Device		1 Package Insert	
On-Call® Diabetes Management Software Kit	G124-13A†	1 USB Data Transfer Cable		1 Installation Disk	

v CE Marked for sale in the European Community **CE** 0123 † US 510(k) Cleared and CLIA Waived



ACON Laboratories, Inc., 10125 Mesa Rim Road, San Diego, CA 92121, USA • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: [info@aconlabs.com](mailto:info@aconlabs.com)

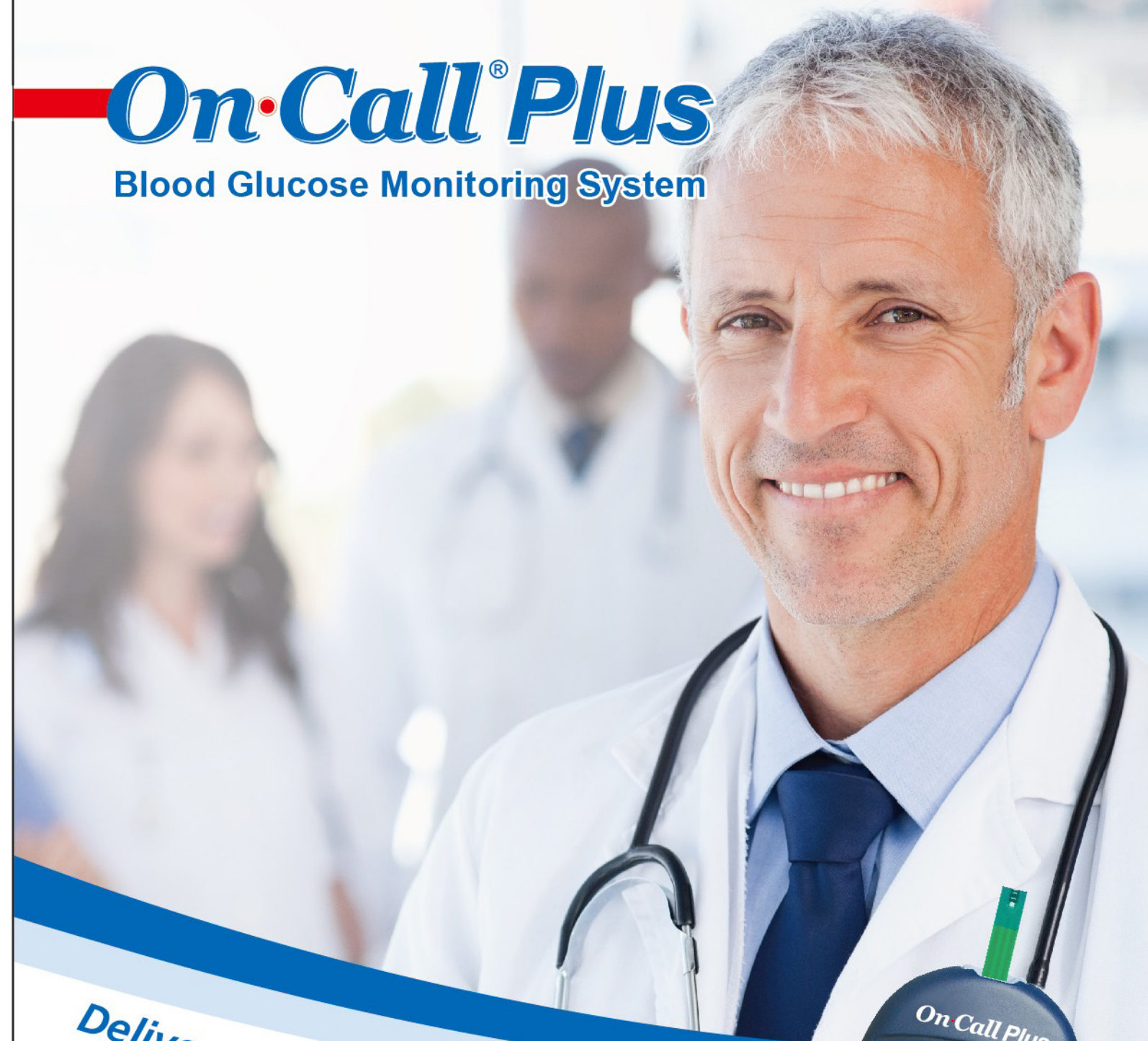
Please visit our website for details: [www.acondiabetescare.com](http://www.acondiabetescare.com)

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# On-Call® Plus

## Blood Glucose Monitoring System



*Delivers Value and Quality*

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

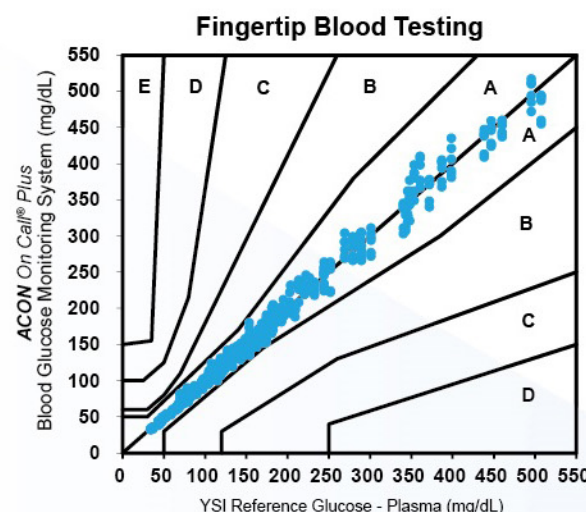
**ACON®**  
Diabetes Care



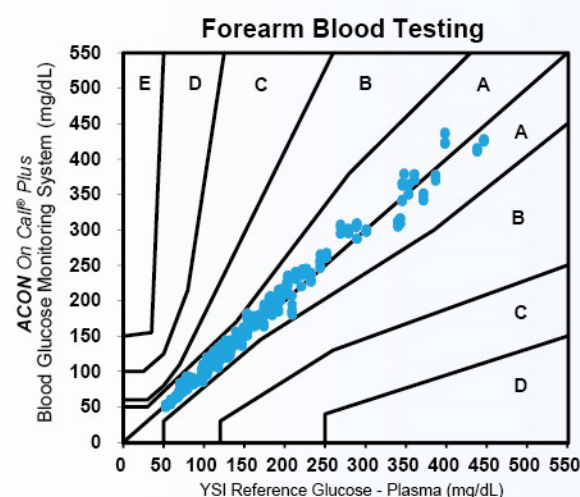


## Accurate and Reliable

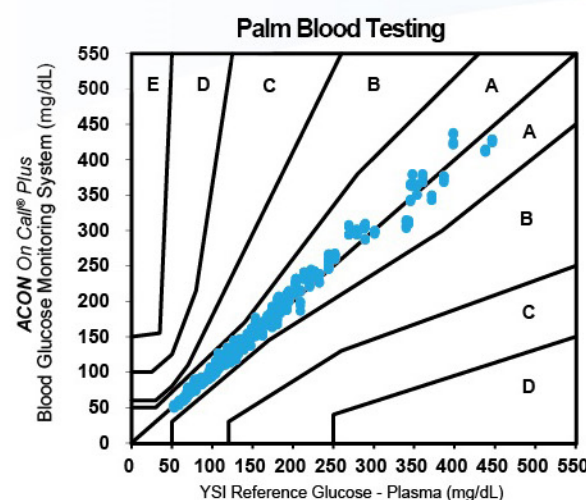
Extensive clinical studies proved the accuracy of *On-Call<sup>®</sup> Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



Consensus Error Grid Analysis Clinical Trial - Fingertip Capillary Blood, by Technican ACON On-Call <sup>®</sup> Plus Blood Glucose Monitoring System vs. YSI			
System Accuracy Results for Glucose Concentration $\geq 100$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	
290 / 462 (62.8%)	432 / 462 (93.5%)	462 / 462 (100.0%)	
System Accuracy Results for Glucose Concentration $< 100$ mg/dL			
Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	
145 / 198 (73.2%)	193 / 198 (97.5%)	198 / 198 (100.0%)	
System Accuracy Results for both Glucose Concentration $\geq 100$ mg/dL and $< 100$ mg/dL			
Within $\pm 15\%$ or $\pm 15$ mg/dL			
658 / 660 (99.7%)			



Consensus Error Grid Analysis Clinical Trial - Forearm Capillary Blood, by Technican ACON On-Call <sup>®</sup> Plus Blood Glucose Monitoring System vs. YSI			
System Accuracy Results for Glucose Concentration $\geq 100$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	
202 / 444 (45.5%)	375 / 444 (84.5%)	440 / 444 (99.1%)	
System Accuracy Results for Glucose Concentration $< 100$ mg/dL			
Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	
110 / 168 (65.5%)	154 / 168 (91.7%)	168 / 168 (100.0%)	
System Accuracy Results for both Glucose Concentration $\geq 100$ mg/dL and $< 100$ mg/dL			
Within $\pm 15\%$ or $\pm 15$ mg/dL			
608 / 612 (99.3%)			



Consensus Error Grid Analysis Clinical Trial - Palm Capillary Blood, by Technican ACON On-Call <sup>®</sup> Plus Blood Glucose Monitoring System vs. YSI			
System Accuracy Results for Glucose Concentration $\geq 100$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	
219 / 444 (49.3%)	395 / 444 (89.0%)	441 / 444 (99.3%)	
System Accuracy Results for Glucose Concentration $< 100$ mg/dL			
Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	
130 / 168 (77.4%)	166 / 168 (98.8%)	168 / 168 (100.0%)	
System Accuracy Results for both Glucose Concentration $\geq 100$ mg/dL and $< 100$ mg/dL			
Within $\pm 15\%$ or $\pm 15$ mg/dL			
609 / 612 (99.5%)			

## Key Features



## Authority Certificate



CE certificate



USFDA CFG certificate



Health Canada certificate



# Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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



Global Diagnostics for Local Markets™

# Urinalysis Reagent Strips

## Simple and Accurate

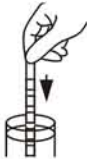
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

## Flexible

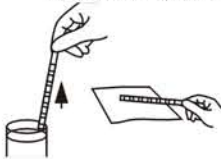
- Compatible for visual and analyzer reading
- More than 30 different combinations available

## Multiple Packaging Options and Long Shelf Life

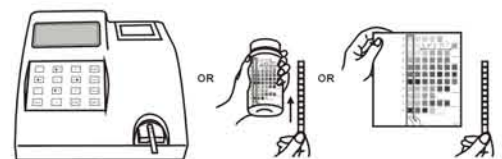
- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!*
  - Single-strip Pouch
    - Individually 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 <sup>♦</sup>		Strips per Canister <sup>◊</sup>	Pouch Packaging <sup>▲</sup>	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 <sup>■</sup>	✓	✓	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

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





# 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 <sup>†</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 16.4" x 16.2" x 12.1"; 176.4 oz		1
U120 Urine Analyzer with Barcode Reader	U111-111 <sup>†</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	44.5 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 <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 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 <sup>†</sup>	1 Data Transfer Cable (RS232C)	1 Package Insert	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	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
- 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 19.5 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
U500 Urine Analyzer	U211-101 <sup>✓</sup>	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 <sup>✓</sup>	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 55.0 cm; 9.2 kg 21.7" x 21.7" x 21.7"; 324.5 oz	1
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 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"; 12.7 oz	50
U500 Data Transfer Kit	U221-131 <sup>✓</sup>	1 Data Transfer Cable (RS232C)	1 Package Insert	12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg 4.7" x 4.7" x 2.6"; 14.1 oz	8

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