



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



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

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.

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



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
in vitro diagnostic device:**

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

classified as Others in the directive 98/79/EC,

**meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic
medical devices which apply to it**

**The self-declaration is according to Annex III
(excluding Section 6) of the Directive.**

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

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



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





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 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

A handwritten signature in black ink, appearing to read "Jassy Alvarenga", is written over a red circular stamp.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc. S.A.

jalvarenga@aconlabs.com

+1 858 875 8085

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:



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*



Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

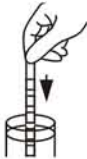
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

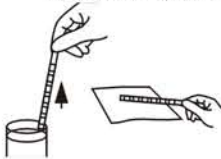
- Compatible for visual and analyzer reading
- More than 30 different combinations available

Multiple Packaging Options and Long Shelf Life

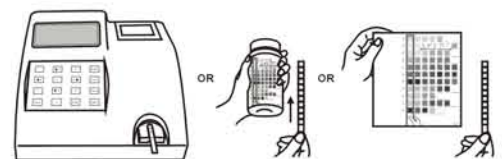
- Canister Packaging
 - Available in 25, 50, 100 and 150 strips per kit
 - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
 - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!*
 - Single-strip Pouch
 - Individually packaged 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 | 100 [■] | ✓ | ✓ | ✓ | | * | * | * | * | * | * | * | * | * | * | * | | | |
| 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 [†] | 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 | 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 [✓] | 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 55.0 cm; 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"; 12.7 oz | 50 |
| U500 Data Transfer Kit | U221-131 [✓] | 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 |

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)



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

Mission[®]

Urine Controls

Simply validate
visual and analyzer
urinalysis with
Mission[®] Liquid and
Dry Strip Urine
Controls!

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



Global Diagnostics for Local Markets™

Mission® Urine Controls

Reliable

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

Quick and Convenient Testing

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

Two Types of Urine Controls Available

Liquid Urine Control

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

Dry Strip Urine Control

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



Specifications

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

Ordering Information

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

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

We also offer other rapid diagnostic and medical products for:

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

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

