



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



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**

**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



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**

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

On Call Plus Blood Glucose Monitoring System,  
On Call Plus Blood Glucose Test Strips,  
On Call EZ II Blood Glucose Monitoring System,  
On Call Redi Blood Glucose Monitoring System,  
On Call Redi II Blood Glucose Test Strips,  
On Call Advanced Blood Glucose Monitoring System,  
On Call Advanced Blood Glucose Test Strips,  
On Call Platinum Blood Glucose Monitoring System,  
On Call Platinum Blood Glucose Test Strips,  
On Call Chosen Blood Glucose Monitoring System,  
On Call Chosen Blood Glucose Test Strips,  
On Call Vivid Blood Glucose Monitoring System (OGM-101),  
On Call Vivid Blood Glucose Test Strips (OGS-101),  
On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),  
On Call Sharp Blood Glucose Monitoring System (OGM-121),  
On Call Sharp Blood Glucose Test Strips (OGS-121),  
On Call Plus II Blood Glucose Monitoring System (OGM-171),  
On Call Plus II Blood Glucose Test Strips (OGS-171),  
On Call Extra Blood Glucose Monitoring System (OGM-191),  
On Call Extra Blood Glucose Test Strips (OGS-191),  
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),  
On Call Blood Ketone Test Strips (OGS-161),  
D-ONE Blood Glucose Monitoring System,  
D-ONE Blood Glucose Test Strips,  
Urinalysis Reagent Strips (Urine),  
UTI Urinary Tract Infection Test Strips,  
Toxoplasma IgG EIA Test Kit,  
Toxoplasma IgM EIA Test Kit,  
Rubella IgG EIA Test Kit,  
Rubella IgM EIA Test Kit,  
CMV IgG EIA Test Kit,

Page 3 of 4

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

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

TÜV®





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

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

# 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

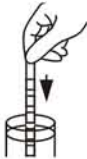
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

## Flexible

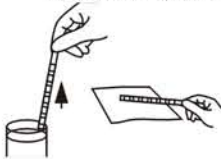
- Compatible for visual and analyzer reading
- More than 30 different combinations available

## Multiple Packaging Options and Long Shelf Life

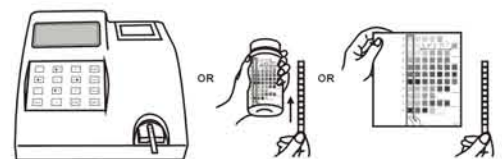
- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!*
  - Single-strip Pouch
    - Individually 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                              | 100 <sup>■</sup>                 | ✓                            | ✓              | ✓    |      | *                                                    | *          | *   | *   | *   | *  | *   | *  | *   | *   | *   |     |     |     |   |
| 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<br>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<br>USB Port for Data Transfer<br>25 Pin Parallel Port for External Printer                                     |
| Capabilities                      | Internal Thermal Printer (included)      RS232C Barcode Reader (optional)<br>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<br>1 Strip holder<br>2 Printer Paper Rolls                              | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Quick Start Guide<br>1 Instruction Manual                                     | 42.0 cm x 41.5 cm x 31 cm; 5.0 kg<br>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<br>1 Strip holder<br>2 Printer Paper Rolls<br>1 Barcode Reader (RS232C) | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Serial Splitter Cable (RS232C)<br>1 Quick Start Guide<br>1 Instruction Manual | 44.5 cm x 44.5 cm x 40.0 cm; 5.5 kg<br>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<br>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<br>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<br>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<br>4.7" x 4.7" x 2.6"; 12.7 oz<br>12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg<br>4.7" x 4.7" x 2.6"; 14.1 oz | 63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg<br>24.8" x 14.6" x 11.8"; 684.3 oz<br>63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg<br>24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz | 50                    |
| U120 Data Transfer Kit                  | U221-131 <sup>†</sup> | 1 Data Transfer Cable (RS232C)                                                           | 1 Package Insert                                                                                                  | 16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg<br>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<br>9.8" x 8.3" x 5.9"; 48.0 oz                                                                                          | 8                     |



# U500 Urine Analyzer



## Accurate and Efficient

- Up to 500 tests/hour for medium/large volume sample testing
- Professional accuracy equivalent to market leader
- Automatic strip detection and alignment for better efficiency
- Test modes include Routine, STAT and QC

## Easy to Operate

- Large touch screen LCD offers simple menu navigation
- Uniquely designed strip platform/waste tray unit for easy one-step cleaning

## Convenient

- Automatic calibration and waste disposal reduce hands-on time
- Can read strips with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request
- Strip selection of up to 4 combinations for analyzer reading
- 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<br>25 Pin Parallel Port for External Printer                                                            |
| Capabilities                      | Internal Thermal Printer (included)      RS232C Barcode Reader (optional)<br>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<br>1 Strip Platform/Waste Tray<br>2 Printer Paper Rolls                              | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Instruction Manual                                            | 51.0 cm x 42.0 cm x 38.5 cm; 7 kg<br>20.1" x 16.5" x 15.2"; 246.9 oz   | 1                     |
| U500 Urine Analyzer with Barcode Reader | U211-111✓   | 1 Urine Analyzer<br>1 Strip Platform/Waste Tray<br>2 Printer Paper Rolls<br>1 Barcode Reader (RS232C) | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Serial Splitter Cable (RS232C)<br>1 Instruction Manual        | 55.0 cm x 55.0 cm x 55.0 cm; 9.2 kg<br>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<br>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<br>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<br>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<br>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](mailto:info@aconlabs.com)  
Please visit our website for details: [www.aconlabs.com](http://www.aconlabs.com)





**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](mailto: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

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](mailto:jalvarenga@aconlabs.com)

+1 858 875 8085

## 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.







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

# 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

# **Mission<sup>®</sup>**

## **Urine Controls**

Simply validate  
visual and analyzer  
urinalysis with  
**Mission<sup>®</sup>** 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<sup>test</sup> and CRE<sup>test</sup>
- Control Level 2 provides positive results for LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB<sup>test</sup> and CRE<sup>test</sup> 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 <sup>†</sup>         | 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 <sup>†</sup> | 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 <sup>†</sup>      | 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**

