



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: March 18, 2024

Signature:

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

Qiyi Xie, Md, MPH
V.P. of Regulatory & Clinical Affairs
ACON Laboratories, Inc.



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.



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

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:**

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".

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

jalvarenga@aconlabs.com

+1 858 875 8085



Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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



ACON®

Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

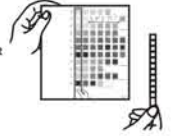
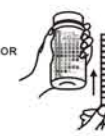
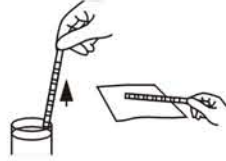
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

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

Multiple Packaging Options and Long Shelf Life

- Canister Packaging
 - Available in 25, 50, 100 and 150 strips per kit
 - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
 - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!*
 - Single-strip Pouch
 - Individually packaged strips with 1, 3, 6 and 20 strips and 1 color chart per kit for OTC or low volume testing
 - Unique packaging maintains 2 year shelf life for all strips in the kit compared to 3 months for remaining strips in an opened canister
 - Multi-strip Pouch
 - Canister Refill Kits with 25 strips/pouch uniquely packaged to save cost for low volume testing and extended shelf life by using the canister for refills



Step 1: Immerse strip into urine

Step 2: Remove excess urine

Step 3: Obtain results by analyzer or visual reading

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

♦Type of Strip:
 Visual Strip Size
 1-6 Parameters: 5 mm x 80 mm; 7-11 Parameters: 5 mm x 108 mm;
 12-13 Parameters: 5 mm x 121 mm
 U120/U500 Strip Size
 1-11 Parameters: 5 mm x 108 mm;
 "E" means extended strip length for 1-6 Parameters

◇ Also available in canisters of 25, 50 and 150 strips
 ▲ Not available in canisters of 150 strips
 ▲ Single-strip Pouch available in 1, 3, 6 and 20 strip kit
 Canister Refill Kit, with 25 strips per pouch or canister, available in 3-pouch and 1- canister kit, or 4-pouch kit



U120 Urine Analyzer



Accurate

- Up to 120 tests/hour in Continuous Test Option
- Capable of reading 1 strip at a time in Single Test Option
- Test modes include Routine, STAT and QC
- Automatic calibration for accurate results and easy operation

Reliable

- Can read up to 4 Strip combinations with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request
- Minimal training required

Convenient Operation

- Saves and recalls the last 2,000 results automatically
- Audible beep signals operator to dip strips in urine
- Can print up to 3 copies per test for convenient reviewing and easy record keeping
- Option to print results on sticker paper for quick and simple record management

Easy Data Management

- Includes RS232C port for easy data transfer to an external computer or LIS
- Optional Barcode Reader to record patient ID

Unique Lockout Functions *new!*

- Strip Lockout
 - Prevents using strips of another brand on the U120 Urine Analyzer
 - Requires barcode reader scan or manual entry of the canister code
- User Lockout
 - Eliminates unapproved users from testing
 - Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings
- QC Lockout
 - Prevents testing without passing QC
 - QC tests can be performed once every 8 hours, day, week or month
 - Analyzer will alert when to run QC test
 - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

Specifications

| Feature | Specifications |
|-----------------------------------|---|
| Analyzer Type | Manual |
| Methodology | Reflectance Photometry |
| Detection | Photosensitive Diode |
| Throughput | Single Test Option: 60 tests/hour Continuous Test Option: 120 tests/hour |
| Test Modes | Routine, STAT and QC |
| Lockout Functions | Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF |
| Memory | Last 2,000 results |
| Strip Incubation Time | 1 Minute |
| Wavelength of Monochromatic LED | 525 nm and 635 nm |
| Standard Strips | 8, 9, 10, 11 Parameters (5 mm x 108 mm) |
| Additional Strips Available | 1-11 Parameters (5 mm x 108 mm); see URS Parameters |
| Total Combinations Per Analyzer | 4 Combinations |
| Analyzer Ports | Standard RS232C Port for Barcode Reader or Data Transfer USB Port for Data Transfer 25 Pin Parallel Port for External Printer |
| Capabilities | Internal Thermal Printer (included) RS232C Barcode Reader (optional) Optional External Printer (not included) USB or RS232C Data Transfer Cable (optional) |
| Major Readable Barcodes | Code 128, Code 39, Codabar (NW-7), Interleaved 25, UPC-A, UPC-E, EAN 8, EAN 13 |
| Calibration | Automatic |
| Available Languages on the Screen | English and additional language(s) |
| Operating Conditions | 0-40°C (32-104°F); ≤ 85% RH |
| Storage Conditions | -5-50°C (23-122°F); ≤ 90% RH |
| Power Source | 100-240 VAC, 50-60 Hz |
| Dimensions (L x W x H) | 27.2 cm x 26.9 cm x 14.6 cm (10.7" x 10.6" x 5.7") |
| Display Dimensions (L x W) | 10.8 cm x 5.7 cm (4.2" x 2.2") |
| Weight | 2.6 kg (5.7 lbs) |

Ordering Information

| Product Name | Catalog No. | Components | Kit Box Dimensions (L x W x H) & Weight | Carton Dimensions (L x W x H) & Weight | Number of Kits/Carton |
|---|-----------------------|--|---|---|-----------------------|
| U120 Urine Analyzer | U111-101 [†] | 1 Urine Analyzer 2 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; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz 12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz | 50 |
| U120 Data Transfer Kit | U221-131 [†] | 1 Data Transfer Cable (RS232C) | 1 Package Insert | 16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz 25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz | 8 |

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

U500 Urine Analyzer



Accurate and Efficient

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

Easy to Operate

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

Convenient

- Automatic calibration and waste disposal reduce hands-on time
- Can read strips with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request
- Strip selection of up to 4 combinations for analyzer reading
- Stores up to 2,000 records and automatically flags abnormal results
- Capable of printing results on sticker paper for quick and easy record management

Data Management Capability

- Includes RS232C port for easy data transfer to an external computer or LIS
- Optional Barcode Reader to record patient ID

Unique Lockout Functions Coming Soon!

- Strip Lockout
 - Prevents using strips of another brand on the U500 Urine Analyzer
 - Requires barcode reader scan or manual entry of the canister code
- User Lockout
 - Eliminates unapproved users from testing
 - Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings
- QC Lockout
 - Prevents testing without passing QC
 - QC tests can be performed once every 8 hours, day, week or month
 - Analyzer will alert when to run QC test
 - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

Specifications

| Feature | Specifications |
|-----------------------------------|--|
| Analyzer Type | Semi-Automatic |
| Methodology | Reflectance Photometry |
| Detection | Photosensitive Diode |
| Throughput | 500 tests/hour (Measuring cycle: 7 seconds/test) |
| Test Modes | Routine, STAT and QC |
| Lockout Functions | Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF |
| Memory | Last 2,000 Records |
| Strip Incubation Time | 1 Minute |
| Wavelength | 525 and 635 nm |
| Standard Strips | 8, 9, 10, 11 Parameters (5 mm x 108 mm) |
| Additional Strips Available | 1-11 Parameters (5 mm x 108 mm); see URS Parameters |
| Total Combinations Per Analyzer | 4 Combinations |
| Waste Disposal Capacity | Up to 150 Strips |
| Analyzer Ports | Standard RS232C Port for Barcode Reader or Data Transfer 25 Pin Parallel Port for External Printer |
| Capabilities | Internal Thermal Printer (included) RS232C Barcode Reader (optional) Optional External Printer (not included) RS232C Data Transfer Cable (optional) |
| Major Readable Barcodes | Code 128, Code 39, Codabar (NW-7), Interleaved 25, UPC-A, UPC-E, EAN 8, EAN 13 |
| Calibration | Automatic |
| Available Languages on the Screen | English and additional language(s) |
| Operating Conditions | 0-40°C (32-104°F); ≤85% RH |
| Storage Conditions | -5-50°C (23-122°F); ≤90% RH |
| Power Source | 100-240 VAC, 50-60 Hz |
| Dimensions (L x W x H) | 36.6 cm x 28.3 cm x 19.5cm (14.4" x 11.1" x 7.7") |
| Display Dimensions (L x W) | 11.5 cm x 9.0 cm (4.5" x 3.5") |
| Weight | 4.0 kg (8.8 lbs) |

Ordering Information

| Product Name | Catalog No. | Components | Kit Box Dimensions (L x W x H) & Weight | Carton Dimensions (L x W x H) & Weight | Number of Kits/Carton |
|---|------------------------|---|---|---|-----------------------|
| U500 Urine Analyzer | U211-101 [✓] | 1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls | 2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual | 51.0 cm x 42.0 cm x 38.5 cm; 7 kg 20.1" x 16.5" x 15.2"; 246.9 oz | 1 |
| U500 Urine Analyzer with Barcode Reader | U211-111 [✓] | 1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls 1 Barcode Reader (RS232C) | 2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Instruction Manual | 55.0 cm x 55.0 cm x 55.0cm; 9.2 kg 21.7" x 21.7" x 21.7"; 324.5 oz | 1 |
| Barcode Reader | U221-111 ^{✓†} | 1 Barcode Reader (RS232C) | 1 Serial Splitter Cable (RS232C) | 23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg 9.3" x 4.3" x 3.1"; 17.0 oz | 22 |
| Printer Paper Rolls | U121-101 | 4 Printer Paper Rolls | Thermal Paper (0.06 m x 20 m): 200 results/roll Sticker Paper (0.06 m x 9 m): 100 results/roll | 12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg 4.7" x 4.7" x 2.6"; 12.7oz 12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg 4.7" x 4.7" x 2.6"; 14.1oz | 50 |
| U500 Data Transfer Kit | U221-131 [✓] | 1 Data Transfer Cable (RS232C) | 1 Package Insert | 16.0 cm x 13.0 cm x 3.5 cm; 0.147kg 6.3" x 5.1" x 1.4"; 5.2 oz | 8 |

We also offer other rapid diagnostic and medical products:

Blood Glucose Monitoring Systems, Immunoassay EIA/ELISA and more.

✓ CE Marked for sale in the European Community **CE**

† Cleared for US 510(k)



| | |
|--------------|---------|
| REF U021-011 | English |
| REF U021-021 | |
| REF U021-031 | |

For validating visual and analyzer reading of urinalysis.
For *in vitro* diagnostic use only.

INTENDED USE

The Liquid Urine Control is intended for use in validating the visual and analyzer reading of urinalysis. The results should be compared to the expected results listed below to ensure the consistent performance of *Mission®* and *Mission® Expert* Urinalysis Reagent Strips and Urine Analyzers. The Liquid Urine Control is available in two levels and is ready to use for monitoring routine urinalysis.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- All materials should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Discard if there is excessive turbidity or evidence of microbial contamination.
- The used materials should be discarded according to local regulations after testing.
- This product is not intended for use as a standard.
- The use of quality control materials is an important part of good laboratory practices. Quality control materials are an objective method of assessing techniques or practices in use.

REAGENTS

The product is a liquid stable control prepared from simulated human urine with added chemicals, constituents of animal origin, preservatives and stabilizers. The control does not include human resource materials. Various pure chemicals are used to adjust each analyte level.

STORAGE AND STABILITY

- Store and ship at 2-8°C (35-46°F). Do not freeze.
- Controls are stable until the expiration date printed on the bottle label when stored at 2-8°C (35-46°F).
- All analytes are stable for 20 days at 2-30°C (35-86°F) once opened and stored with the cap on tightly.

MATERIALS

Materials Provided

- Liquid Urine Control Level 1 and/or Level 2
 - Package Insert

Materials Required But Not Provided

- Strips
 - Timer

DIRECTIONS FOR USE

Allow all test materials to reach room temperature (15-30°C) prior to testing.

- Invert the urine control bottle 3 times to ensure reproducible results, then remove the cap. While holding the urinalysis reagent strip, invert the urine control bottle and gently squeeze the urine control bottle to dispense the urine control. Ensure each reagent area on urinalysis reagent strip is completely saturated with urine control. See illustration 1 below.

Note:

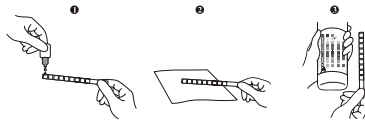
- Do not touch the tip of the urine control bottle to the reagent areas on the urinalysis reagent strip to avoid contamination.
 - Dispense the remaining hanging drop of urine control before turning the urine control bottle upright.
- Dispose of the hanging drop of urine control to avoid contaminating the unused control with reagents from the urinalysis reagent strip.

- Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with the urine control. See illustration 2 below.
- Compare the reagent areas to the corresponding color blocks on the canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

Note:

- Results may be read up to 2 minutes after the specified times.
- Results may also be read using the *Mission®* and *Mission® Expert* Urine Analyzers. Refer to the Instruction Manual for details.

- Clean the dropper tip, and immediately replace the cap tightly.



EXPECTED VALUES

The expected values listed on the following page should only be used for the specific lots printed. Expected values were obtained from replicate analysis. The urine control and urinalysis reagent strip lots can create slight differences in expected results. Different laboratory methods, instruments and reagents can create variations between laboratories and variations over time. Use the results provided as reference only. It is recommended that each laboratory establish its own parameters of precision.

Note: The color reactions of Urobilinogen and Bilirubin reagent areas on the urinalysis reagent strips may produce colors that are atypical when visually compared to the color blocks on the color chart.

LIMITATIONS

The *Mission®* Liquid Urine Control can only be used with *Mission®* and *Mission® Expert* Urinalysis Reagent Strips and Urine Analyzers. Ensure reproducible results by inverting the urine control bottle 3 times before each use. Interpretation of visual results depends on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the color chart does not correspond to a specific concentration, but it does correspond to a range of analyte concentrations.

Index of Symbols

| | | | | | |
|--|---|--|---------------|--|---------------------------|
| | Attention, see instructions for use | | Tests per kit | | Manufacturer |
| | For <i>in vitro</i> diagnostic use only | | Use by | | Authorized Representative |
| | Store between 2-8°C | | Lot Number | | Catalog # |



ACON Laboratories, Inc.
10125 Mesa Rim Road,
San Diego, CA 92121, USA



EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Mission® Urinalysis Reagent Strips (Urine)

Package Insert

| | | | |
|--------------|--------------|--------------|---------|
| REF U031-011 | REF U031-051 | REF U031-091 | English |
| REF U031-021 | REF U031-061 | REF U031-101 | |
| REF U031-031 | REF U031-071 | REF U031-111 | |
| REF U031-041 | REF U031-081 | | |

For rapid detection of multiple analytes in human urine.
For *in vitro* diagnostic use only.

INTENDED USE

The Urinalysis Reagent Strips (Urine) are firm plastic strips onto which several separate reagent areas are affixed. The test is for the qualitative and semi-quantitative detection of one or more of the following analytes in urine: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes.

SUMMARY

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Urinalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. The Urinalysis Reagent Strips (Urine) can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.^{1,2}

PRINCIPLE AND EXPECTED VALUES

Ascorbic acid: This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange. Patients with adequate diet may excrete 2-10 mg/dL daily. After ingesting large amounts of ascorbic acid, levels can be around 200 mg/dL.

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Glucose should not be detected in normal urine. Small amounts of glucose may be excreted by the kidney.³ Glucose concentrations as low as 100 mg/dL may be considered abnormal if results are consistent.

Bilirubin: This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.^{4,6} In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.⁷

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.035.⁸ Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022.³ In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue. Any green spots or green color development on the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females. The significance of a trace reading varies among patients and clinical judgment is required in these specimens.

pH: This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens from newborns is pH 5-7.⁹ The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.⁹

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. 1-14 mg/dL of protein may be excreted by a normal kidney.¹⁰ A color matching any block greater than trace indicates significant proteinuria. Clinical judgment is required to evaluate the significance of trace results.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen in strongly acidic medium to produce a pink color. Urobilinogen is one of the major compounds produced in heme synthesis and is a normal substance in urine. The expected range for normal urine with this test is 0.2-1.0 mg/dL (3.5-17 µmol/L).⁸ A result of 2.0 mg/dL (35 µmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl) ethylenediamine to produce a pink color. Nitrite is not detectable in normal urine.⁹ The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen from the same patient. Repeated trace and positive results are of clinical significance.

REAGENTS AND PERFORMANCE CHARACTERISTICS

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter.

| Reagent | Read Time | Composition | Description |
|-----------------------|-------------|--|--|
| Ascorbic Acid (ASC) | 30 seconds | 2,6-dichlorophenolindophenol; buffer and non-reactive ingredients | Detects ascorbic acid as low as 5-10 mg/dL (0.28-0.56 mmol/L). |
| Glucose (GLU) | 30 seconds | glucose oxidase; peroxidase; potassium iodide; buffer; non-reactive ingredients | Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L). |
| Bilirubin (BIL) | 30 seconds | 2,4-dichloroaniline diazonium salt; buffer and non-reactive ingredients | Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 µmol/L). |
| Ketone (KET) | 40 seconds | sodium nitroprusside; buffer | Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L). |
| Specific Gravity (SG) | 45 seconds | bromthymol blue indicator; buffer and non-reactive ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide | Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ± 0.005. |
| Blood (BLO) | 60 seconds | 3,3',5,5'-tetramethylbenzidine (TMB); diisopropylbenzene dihydroperoxide; buffer and non-reactive ingredients | Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/µL in urine specimens with ascorbic acid content of < 50 mg/dL. |
| pH | 60 seconds | methyl red sodium salt; bromthymol blue; non-reactive ingredients | Permits the quantitative differentiation of pH values within the range of 5-9. |
| Protein (PRO) | 60 seconds | tetrabromophenol blue; buffer and non-reactive ingredients | Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L). |
| Urobilinogen (URO) | 60 seconds | p-diethylaminobenzaldehyde; buffer and non-reactive ingredients | Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 µmol/L). |
| Nitrite (NIT) | 60 seconds | p-arsanilic acid; N-(1-naphthyl) ethylenediamine; non-reactive ingredients | Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid. |
| Leukocytes (LEU) | 120 seconds | derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients | Detects leukocytes as low as 9-15 white blood cells Leu/µL in clinical urine. |

The performance characteristics of the Urinalysis Reagent Strips (Urine) have been determined in both laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed. Please refer to the Limitations section in this package insert.

Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the chart corresponds to a range of analyte concentrations.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The strip should remain in the closed canister until use.
- Do not touch the reagent areas of the strip.
- Discard any discolored strips that may have deteriorated.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.

STORAGE AND STABILITY

Store as packaged in the closed canister either at room temperature or refrigerated (2-30°C). Keep out of direct sunlight. The strip is stable through the expiration date printed on the canister label. Do not remove the desiccant. Remove only enough strips for immediate use. Replace cap immediately and tightly. **DO NOT FREEZE.** Do not use beyond the expiration date.

Note: Once the canister has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose.

Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

MATERIALS

Materials Provided

- Strips
- Package insert

Materials Required But Not Provided

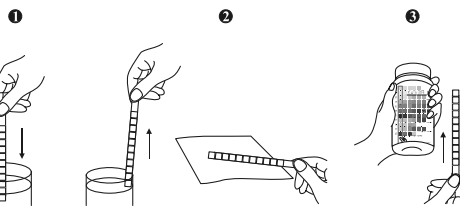
- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the strip, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

- Remove the strip from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of strip(s). Completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents. See illustration 1 below.
- While removing the strip from the urine, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine. See illustration 2 below.
- Compare the reagent areas to the corresponding color blocks on the canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

Note: Results may be read up to 2 minutes after the specified times.



INTERPRETATION OF RESULTS

Results are obtained by direct comparison of the color blocks printed on the canister label. The color blocks represent nominal values; actual values will vary close to the nominal values. In the event of unexpected or questionable results, the following steps are recommended: confirm that the strips have been tested within the expiration date printed on the canister label, compare results with known positive and negative controls and repeat the test using a new strip. If the problem persists, discontinue using the strip immediately and contact your local distributor.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance.

LIMITATIONS

Note: The Urinalysis Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®. Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.⁸ The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.

Ascorbic acid: No interference is known.
Glucose: The reagent area does not react with lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Sensitivity may be decreased in specimens with high specific gravity (>1.025) and with ascorbic acid concentrations of ≥ 25 mg/dL. High ketone levels ≥ 100 mg/dL may cause false negative results for specimens containing a small amount of glucose (50-100 mg/dL).

Bilirubin: Bilirubin is absent in normal urine, so any positive result, including a trace positive, indicates an underlying pathological condition and requires further investigation. Reactions may occur with urine containing large doses of chlorpromazine or rifampin that might be mistaken for positive bilirubin.⁹ The presence of bilirubin-derived bile pigments may mask the bilirubin reaction. This phenomenon is characterized by color development on the test patch that does not correlate with the colors on the color chart. Large concentrations of ascorbic acid may decrease sensitivity.

Ketone: The test does not react with acetone or β-hydroxybutyrate.⁸ Urine specimens of high pigment, and other substances containing sulfhydryl groups may occasionally give reactions up to and including trace (±).⁹

Specific Gravity: Ketoacidosis or protein higher than 300 mg/dL may cause elevated results. Results are not affected by non-ionic urine components such as glucose. If the urine has a pH of 7 or greater, add 0.005 to the specific gravity reading indicated on the color chart.

Blood: A uniform blue color indicates the presence of myoglobin, hemoglobin or hemolyzed erythrocytes.⁸ Scattered or compacted blue spots indicate intact erythrocytes. To enhance accuracy, separate color scales are provided for hemoglobin and for erythrocytes. Positive results with this test are often seen with urine from menstruating females. It has been reported that urine of high pH reduces sensitivity, while moderate to

high concentration of ascorbic acid may inhibit color formation. Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

pH: If the procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing the pH result to appear artificially low. pH readings are not affected by variations in urinary buffer concentration.

Protein: Any green color indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein.⁸ A negative result does not rule out the presence of these other proteins. False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results.⁸ The urine specimens with high specific gravity may give false negative results.

Urobilinogen: All results lower than 1 mg/dL urobilinogen should be interpreted as normal. A negative result does not at any time preclude the absence of urobilinogen. The reagent area may react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamides.⁹ False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.

Nitrite: The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red color should be interpreted as a positive result, suggesting the presence of nitrite. Color intensity is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Comparing the reacted reagent area on a white background may aid in the detection of low nitrite levels, which might otherwise be missed. Ascorbic acid above 30 mg/dL may cause false negatives in urine containing less than 0.05 mg/dL nitrite ions. The sensitivity of this test is reduced for urine specimens with highly buffered alkaline urine or with high specific gravity. A negative result does not at any time preclude the possibility of bacteruria. Negative results may occur in urinary tract infections from organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder for a sufficient length of time (at least 4 hours) for reduction of nitrate to nitrite to occur; when receiving antibiotic therapy or when dietary nitrate is absent.

Leukocytes: The result should be read between 60-120 seconds to allow for complete color development. The intensity of the color that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations (≥ 2,000 mg/dL) may cause test results to be artificially low. The presence of cephalixin, cephalothin, or high concentrations of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein may diminish the intensity of the reaction color. This test will not react with erythrocytes or bacteria common in urine.⁸

BIBLIOGRAPHY

- Free AH, Free HM. *Urinalysis, Critical Discipline of Clinical Science*. CRC Crit. Rev. Clin. Lab. Sci. 3(4): 481-531, 1972.
- Yoder J, Adams EC, Free, AH. *Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH*. Amer. J. Med Tech. 31:285, 1965.
- Shchersten B, Fritz H. *Subnormal Levels of Glucose in Urine*. JAMA 201:129-132, 1967.
- McGarry JD, Lilly. Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, 1978.
- Williamson DH. *Physiological Ketoses, or Why Ketone Bodies?* Postgrad. Med. J. (June Suppl.): 372-375, 1971.
- Paterson P, et al. *Maternal and Fetal Ketone Concentrations in Plasma and Urine*. Lancet: 862-865; April 22, 1967.
- Fraser J, et al. *Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk*. Clin. Chem. Acta II: 372-378, 1965.
- Henry JB, et al. *Clinical Diagnosis and Management by Laboratory Methods*, 20th Ed. Philadelphia. Saunders. 371-372, 375, 379, 382, 385, 2001.
- Tietz NW. *Clinical Guide to Laboratory Tests*. W.B. Saunders Company. 1976.
- Burtis CA, Ashwood ER. *Tietz Textbook of Clinical Chemistry* 2nd Ed. 2205, 1994.

Index of Symbols

| | | | | | |
|--|---|--|---------------|--|--------------|
| | Consult instructions for use | | Tests per kit | | Manufacturer |
| | For <i>in vitro</i> diagnostic use only | | Use by | | Do not reuse |
| | Store between 2-30°C | | Lot Number | | Catalog # |
| | Authorized Representative | | | | |

ACON Laboratories, Inc.
10125 Mesa Rim Road,
San Diego, CA 92121, USA

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany