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: 

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

Digitally signed by Dolgopol Iulian
Date: 2024.11.27 15:11:30 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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.

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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

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

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

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

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

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

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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

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

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

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TÜV®

Declaration of Conformity

We, the manufacturer, under compliance to Article 17 of regulation (EU) 2017/746, declare under our sole responsibility that the medical device:

Device Name	REF Number
Mission® Expert U500 Urine Analyzer	U213-101, U213-111
Mission® Expert U500 Data Transfer Kit	U223-131
Mission® Expert Barcode Reader	U223-111
Mission® Expert Printer Paper Rolls	U123-101
Insight® Expert U500 Urine Analyzer	U213-105, U213-115
Insight® Expert U500 Data Transfer Kit	U223-135
Insight® Expert Barcode Reader	U223-115
Insight® Expert Printer Paper Rolls	U123-105

of class A according to Rule 5(b) of Annex VIII of regulation (EU) 2017/746, is in conformity with

Regulation (EU) IVDR 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

and

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and further amendments to the directive issued and in force at the date of this declaration.*

It has been demonstrated that the requirements specified in Article 4 have been met.

The materials in ACON's products are assessed in accordance with ACON's procedure for approval which uses documents and contractual agreements to evaluate compliance and approve new materials and components.*

This declaration is based on:

Manufacturer's Name: ACON Laboratories, Inc.

Manufacturer's Address: 5850 Oberlin Drive, #340 San Diego, CA 92121

Manufacturer's SRN: US-MF-000023913

Authorized Representative Name: Medical Device Safety Service GmbH

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI: 682607999999004 54H

Intended Purpose of device: The Expert U500 Urine Analyzer is intended for use in conjunction with the Expert Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in human urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes, Ascorbic Acid, Albumin, and Creatinine, as well as the qualitative detection of Nitrite. The instrument is intended for professional, in vitro diagnostic use only.

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

Signed this 20 day of May, 2022
in San Diego, CA USA

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

* This statement is based on information and data provided by third parties and may not have been verified through destructive testing or other chemical analysis.

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

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

ACON LABORATORIES, INC. S.A.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc.
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® 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.

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

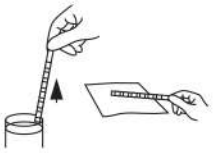
Flexible

- Compatible for visual and analyzer reading
- Over 35 different combinations available

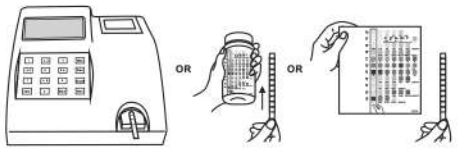
Multiple Packaging Options and Long Shelf Life

- Canister Packaging
  - Available in 25, 50 and 100 strips per canister
  - 2 year shelf life for unopened canisters which 150 strips per kit without MA/CRE Combo offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging
  - Individually packaged strips available in kit of 3 or 6 strips for visual reading only (includes 1 color chart)
  - Unique packaging maintains 2 year shelf life for all strips in the kit compared to 3 months for remaining strips in an opened canister

Step 1: Immerse strip into urine



Step 2: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

No.	Catalog No.	No. of Parameters	Type of Strip§		Reading Availability				Parameters													
			Visual Reading	Analyzer Reading	Visual	U120	U120 Ultra	U500	ASC	GLU	BIL	KET	SG	BLO	PH	PRO	URO	NIT	LEU	ALB	CRE	CA
1	U031-141	14	14C√		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*	*	*	
2	U031-131	13	13CE√		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*	*	*	
3	U031-111	11	11A√†		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*			
4	U031-101	10	10U√x		Yes	Yes	Yes	Yes		*	*	*	*	*	*	*	*	*	*			
5	U031-191	9	9U√x		Yes	Yes	Yes	Yes		*	*	*	*	*	*	*	*	*				
6	U031-081	8	8U√x		Yes	Yes	Yes	Yes		*	*	*		*	*	*	*	*				
7			8N√x		Yes	Yes	Yes	Yes		*		*	*	*	*	*		*	*			
8			8S√x		Yes	Yes	No	Yes		*			*	*	*	*	*	*	*			
9			*8K*√x		Yes	Yes	No	Yes		*	*	*			*	*	*	*	*			
10	U031-071	7	7N√x		Yes	Yes	Yes	Yes		*		*		*	*	*		*	*			
11	U031-061	6	6N√x	6NE√x	Yes	Yes	No	Yes		*				*	*	*		*	*			
12			6U√x	6UE√x	Yes	Yes	No	Yes			*		*	*		*	*	*				
13	U031-051	5	5B√x	5BE√x	Yes	Yes	No	No		*		*		*	*	*						
14			5N√x	5NE√x	Yes	Yes	Yes	No		*				*		*		*	*			
15			*5S*√x	*5SE*√x	Yes	Yes	No	No		*			*	*	*	*						
16			*5U*√x	*5UE*√x	Yes	Yes	No	No			*			*			*	*	*			
17	U031-041	4	4P√x	4PE√x	Yes	Yes	Yes	Yes		*						*		*	*			
18			4S√x	4SE√x	Yes	Yes	Yes	Yes		*			*		*	*						
19			4B√x	4BE√x	Yes	Yes	No	No		*				*	*	*						
20			4K√x	4KE√x	Yes	Yes	Yes	Yes		*		*			*	*						
21			4G√x	4GE√x	Yes	Yes	No	No		*				*		*			*			
22			4N√x	4NE√x	Yes	Yes	No	Yes						*		*		*	*			
23	U031-031	3	3P√x	3PE√x	Yes	Yes	Yes	Yes		*					*	*						
24			3K√x	3KE√x	Yes	Yes	Yes	Yes		*		*				*						
25			*3G*√x	*3GE*√x	Yes	Yes	No	Yes		*		*			*							
26			3N√x	3NE√x	Yes	Yes	No	Yes						*				*	*			
27	U031-021	2	2G√x	2GE√x	Yes	Yes	Yes	Yes		*						*						
28			2K√x	2KE√x	Yes	Yes	Yes	Yes		*		*										
29			2N√x	2NE√x	Yes	Yes	Yes	Yes										*	*			
30			2B√x	2BE√x	Yes	Yes	No	Yes						*					*			
31			2U√x	2UE√x	Yes	Yes	No	Yes			*						*					
32			*2S*√x	*2SE*√x	Yes	Yes	No	Yes					*		*							
33			2C√	2CE√	Yes	Yes	Yes	Yes												*	*	
34	U031-011	1	*1B*√x	*1BE*√x	Yes	Yes	No	No						*								
35			1P√x	1PE√x	Yes	Yes	No	No							*							
36			1G√x	1GE√x	Yes	Yes	Yes	No		*												
37			1K√x	1KE√x	Yes	Yes	No	No				*										
38			1R√x	1RE√x	Yes	Yes	No	No								*						

§Type of Strip:
Visual Strip Size: 1-6 Parameters: 80 mm x 5 mm; 7-14 Parameters: 108 mm x 5 mm
U120/U500 Strip Size: 1-14 Parameters: 108 mm x 5 mm
"E" means extended strip length for 1-6 Parameters and exclusive strip length for 13 Parameter
Default Type of Strip (U120/U500): 11A, 10U, 9U and 8N
Standard Black Canisters : Available for 25, 50 and 100 strips; 150 strips per kit without MA/CRE Combo
Pouch: Single-strip pouch available in kit of 3 or 6 for visual reading only

√ CE Marked for sale in the European Community
† FDA 510(k) Cleared
x FDA 510(k) Cleared and CLIA Waived

U120 Urine Analyzer

Accurate
- Up to 120 tests/hour in Continuous Test Option
- Test categories include Routine, STAT and QC
- Automatic calibration for accurate results and easy operation

Reliable
- Can read strips with up to 14 parameters, including Microalbumin/Creatinine/Calcium
- 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 and USB ports for easy data transfer to an external computer or LIS
- Record Operator/Patient ID by Manual Entry and Barcode Reader

Specifications

Features	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	Single Test Option: 60 tests/hour Continuous Test Option: 120 tests/hour
Test Categories	Routine, STAT and QC
Memory	Last 2,000 results
Strip Incubation Time	1 Minute
Wavelength of Monochromatic LED	525 nm and 635 nm
Default Strips	8, 9, 10, 11 Parameters (108 mm x 5 mm)
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Total Combinations Per Analyzer	4 Combinations
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer USB Port for Data Transfer 25 Pin Parallel Port for External Printer
Data Entry Capabilities	Operator/Patient ID - Manual Entry and Barcode Reader (Up to 20 characters)
Connection 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), EAN 8, EAN 13, Interleave 25 , UPCA, UPCE
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) without batteries or power supply

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√X	1 Urine Analyzer 1 Strip Holder 2 Printer Paper Rolls 2 Fuses (2.0A) 1 Power Cord 1 Quick Start Guide 1 Instruction Manual	42.0 cm x 41.5 cm x 31 cm; 5.0 kg 16.4" x 16.2" x 12.1"; 176.4 oz		1
U120 Urine Analyzer with Barcode Reader	U111-111√X	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	44.5cm x 44.5cm x 40.0cm; 5.5 kg 17.5" x 17.5" x 15.7"; 194 oz		1
Barcode Reader	U221-111√X	1 Barcode Reader (RS232C) 1 Serial Splitter Cable (RS232C)	23.6 cm x10.8 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	12.0 cm x 12.0 cm x 6.5 cm; 0.36kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
		4 Printer Paper Rolls — Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
U120 Data Transfer Kit	U221-131√X	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

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X **FDA 510(k) Cleared and CLIA Waived**

U120 Ultra Urine Analyzer

Easy to Operate
- Large color touchscreen LCD for simple menu navigation
- Work List and Help Menu available for specimen review and troubleshooting
- Powered by AC adaptor or 6 AA batteries for easy portability
- Up to 2,000 patient memory and 800 Operator ID storage
- Ability to select Time Logout between 1-99 with minutes or hours option

Accurate and Efficient
- Advanced CMOS Image Sensor ensures accurate readings
- Can read strips with up to 14 parameters, including Microalbumin, Creatinine and Calcium
- Option to edit test number sequence, or skip then return to specific test numbers
- Ability to edit abnormal results

Simple Data Transfer
- Immediate transmission of LIS data using Bluetooth, LAN or WLAN
- Ability to update software with SD card or USB flash drive

Unique Lockout Functions
- Strip Lockout
  - Pre-set option to prevent using strips of another brand, with a barcode reader or by manual entry
- User Lockout
  - Option to eliminate unapproved users with up to 800 operators
- QC Lockout
  - Prevents testing without passing QC
  - 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	CMOS Image Sensor
Throughput	Single Test Option: 55 tests/hour; Continuous Test Option: 120 tests/hour
Test Modes	Quick Test Mode, Full Test Mode and Customized Test Mode
Test Category	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	390 nm - 770 nm
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations Per Analyzer	Over 15 Combinations
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer and External Printer USB Ports for Keyboard or Data Transfer
Data Entry Capabilities	Operator ID, Patient ID/Name - Manual Entry and Barcode Reader (Up to 20 characters) Urine Color and Clarity, Strip Lot Number, and Expiration Date - Manual Entry
Connection Capabilities	Internal Thermal Printer (included) Bluetooth (included) Bluetooth Adaptor (optional) RS232C Barcode Reader (optional) USB or RS232C Data Transfer Cable (optional) SD Card or USB flash drive for Software Update (optional) Ethernet via USB to RJ45 Adapter (optional) Keyboard (not included) Optional External Printer (not included)
Major Readable Barcodes	Code 39, Code 93, Code 128, Codabar (NW-7), EAN 8, EAN 13, EAN 128, French Pharmacode, Industrial 25, Interleave 25, Italy Pharmacode, Matrix 25, MSI, Plessey, RSS, Telepen, UPCA, UPCE
Screen Type	Large color touch screen LCD (12 cm x 9 cm)
LIS Interface	Formatted and compatible with HL-7 compliant, *ACON* standard interface, S interface, D interface, U interface and R interface for downloading of LIS data
Calibration	Automatic
Available Languages on the Screen	More than 10 languages available, including English
Analyzer Operating Conditions	0-40°C (32-104°F); 5%-85% RH
System Operating Conditions	15-30°C (59-86°F); 20%-80% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100- 240 VAC, 45-65 Hz; 6 AA Alkaline Batteries
Line Leakage Current	0.5 mA
Dimensions (L x W x H)	26 cm x 15 cm x 18 cm (10" x 6" x 7")
Display Dimensions (L x W)	12 cm x 9 cm (5" x 4")
Weight	1.7 kg (3.7 lb) without batteries or power supply

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 Ultra Urine Analyzer	U114-101√	1 Urine Analyzer 2 Test Tables 2 Test Table Inserts 2 Printer Paper Rolls 1 Power Cord and Supply Adapter 1 Brush 1 Quick Start Guide 1 Instruction Manual		40 cm × 39 cm × 36 cm; 4 kg 16" x 15" x 14"; 141 oz		1
U120 Ultra Urine Analyzer with Barcode Reader	U114-111√	1 Urine Analyzer 2 Test Tables 2 Test Table Inserts 2 Printer Paper Rolls 1 Barcode Reader (RS232C) 1 Power Cord and Supply Adapter 1 Brush 1 Quick Start Guide 1 Instruction Manual		40 cm × 39 cm × 36 cm; 4 kg 16" x 15" x 14"; 141 oz		1
Barcode Reader	U124-111√	1 Barcode Reader (RS232C)		23.6 cm x10.8 cm x 7.8 cm; 0.36 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	12.0 cm x 12.0 cm x 6.5 cm; 0.36 kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
			Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
U120 Ultra Data Transfer Kit	U124-131√	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

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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 categories 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 up to 14 parameters, including Microalbumin/Creatinine/Calcium
- 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
- Record Operator/Patient ID by Manual Entry and Barcode Reader

Unique Lockout Functions
- Strip Lockout
  - Pre-set option to prevent using strips of another brand, with a barcode reader or by manual entry
- User Lockout
  - Option to eliminate unapproved users with up to 10 operators
- QC Lockout
  - Prevents testing without passing QC
  - 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 Categories	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
Default Strips	8, 9, 10, 11 Parameters (108 mm x 5 mm)
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations Per Analyzer	4 Combinations
Waste Disposal Capacity	Up to 150 Strips
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer 25 Pin Parallel Port for External Printer
Data Entry Capabilities	Operator/Patient ID - Manual Entry and Barcode Reader (Up to 25 characters)
Connection 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), EAN 8, EAN 13, Interleave 25, UPCA, UPCE
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) without batteries or power supply

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 x10.8 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 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	12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
			Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg 4.7" x 4.7" x 2.6"; 14.1oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
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	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

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† FDA 510(k) Cleared

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

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
    - Dropper tip bottles provide efficient use of the control solution
    - Easily drop the control solution onto each reagent pad using the dropper tip bottle
    - Controls can be used up to 40 times within 30 days at room temperature
  - Diptubes
    - Diptube packaging allows for quick testing similar to using a urine specimen
    - Simply dip the strip into the control solution and read results
    - Controls 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, CA (13)		
Solution Detection Levels	Level 1	Negative: LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE, CA		
	Level 2	Positive: LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB CRE, CA and 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 √X	U021-011	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
Liquid Diptube Urine Control √X	U021-071	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
Dry Strip Urine Control √X	U021-041	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

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Mission®

Liquid Urine Control
Expected Values

Mission® Urinalysis Reagent Strips Visual Reading

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)			Level 1 (14C and 13CE) (Lot#17110079)			Level 2 (14C and 13CE) (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Leukocytes (LEU)	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+	Negative	Negative	–	Positive	Positive	+
Urobilinogen (URO)	0.2 – 1mg/dL	3.5 – 17µmol/L	– - ±	2 – 12 mg/dL	35 – 200µmol/L	1+ – 4+	0.2 – 1 mg/dL	3.5– 17µmol/L	– - ±	2 – 12 mg/dL	35 – 200µmol/L	1+ – 4+
Protein (PRO)	Negative	Negative	–	30 – 2000mg/dL	0.3 – 20.0g/L	1+ – 4+	Negative	Negative	–	30 – 2000mg/dL	0.3 – 20.0g/L	1+ – 4+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0
Blood (BLO)	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015–1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025	1.015-1.030	1.015 – 1.030	1.015–1.030	1.005-1.025	1.005 – 1.025	1.005 – 1.025
Ketone (KET)	Negative	Negative	–	5 – 160mg/dL	0.5-16.0mmol/L	± – 4+	Negative	Negative	–	5-160mg/dL	0.5-16.0mmol/L	± – 4+
Bilirubin (BIL)	Negative	Negative	–	1 – 4 mg/dL	17 – 70µmol/L	1+ – 3+	Negative	Negative	–	1 – 6 mg/dL	17 – 100µmol/L	1+ – 3+
Glucose (GLU)	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	± – 3+	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	1+ – 4+
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–
Microalbumin (ALB)	10 – 30mg/L	10 – 30mg/L	10 – 30mg/L	80 – 150mg/L	80 – 150mg/L	80 – 150mg/L	10 – 30mg/L	10 – 30mg/L	10 – 30mg/L	80 – 150mg/L	80 – 150mg/L	80 – 150mg/L
Creatinine (CRE)	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100 –300mg/dL	8.8-26.5mmol/L	100 –300mg/dL	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100-300mg/dL	8.8-26.5mmol/L	100 –300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	NA	NA	NA	NA	NA	NA
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Calcium (CA)	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL

Mission® Urinalysis Reagent Strips Analyzer Reading with *Mission*® U120/U500/U120 Ultra*

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)			Level 1 (14C and 13CE) (Lot#17110079)			Level 2 (14C and 13CE) (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Leukocytes (LEU)	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+	Negative	Negative	–	Positive	Positive	+
Urobilinogen (URO)	0.2 – 1mg/dL	3.5 – 17µmol/L	– - ±	2 – 8 mg/dL	35 – 140µmol/L	1+ – 3+	0.2 – 1 mg/dL	3.5– 17µmol/L	– - ±	2 – 8 mg/dL	35 – 140µmol/L	1+ – 3+
Protein (PRO)	Negative	Negative	–	30 – 300mg/dL	0.3 – 3.0g/L	1+ – 3+	Negative	Negative	–	30 – 300mg/dL	0.3 – 3.0g/L	1+ – 3+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0
Blood (BLO)	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015–1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025	1.015-1.030	1.015 – 1.030	1.015–1.030	1.005-1.025	1.005 – 1.025	1.005 – 1.025
Ketone (KET)	Negative	Negative	–	5 – 80mg/dL	0.5-8.0mmol/L	± – 3+	Negative	Negative	–	5-80mg/dL	0.5-8.0mmol/L	± – 3+
Bilirubin (BIL)	Negative	Negative	–	1 – 4 mg/dL	17 – 70µmol/L	1+ – 3+	Negative	Negative	–	1 – 6 mg/dL	17 – 100µmol/L	1+ – 3+
Glucose (GLU)	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	± – 3+	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	1+ – 4+
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–
Microalbumin (ALB)	10 – 30mg/L	10 – 30mg/L	10 – 30mg/L	80-150mg/L	80 – 150mg/L	80 – 150mg/L	10-30mg/L	10 – 30mg/L	10 – 30mg/L	80 – 150mg/L	80 – 150mg/L	80 – 150mg/L
Creatinine (CRE)	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100 –300mg/dL	8.8-26.5mmol/L	100 –300mg/dL	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100-300mg/dL	8.8-26.5mmol/L	100 –300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	NA	NA	NA	NA	NA	NA
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Calcium (CA)	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL

Mission® *Expert* Urinalysis Reagent Strips Visual Reading

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–
Blood (ERY, Hb)	Negative	Negative	–	Ca.25 – Ca.250 Ery/µl	Ca.25 – Ca.250 Ery/µl	2+ – 4+
Bilirubin (BIL)	Negative	Negative	–	1– 6 mg/dL	17 – 100µmol/L	1+ – 3+
Urobilinogen (URO)	0.2 mg/dL	3.5 µmol/L	–	4 – 12 mg/dL	70 – 200 µmol/L	2+ – 4+
Ketone Bodies (KET)	Negative	Negative	–	10 – 150 mg/dL	1.0 – 15.0 mmol/L	1+ – 3+
Glucose (GLU)	Negative	Negative	–	100 – 1000 mg/dL	5.5 – 56 mmol/L	2+ – 4+
Protein (PRO)	Negative	Negative	–	30 – 500 mg/dL	0.3 – 5.0 g/L	1+ – 3+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+
Leukocytes (LEU)	Negative	Negative	–	ca. 10-25 – ca. 500 Leu/µl	ca. 10-25 – ca. 500 Leu/µl	1+ – 3+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	7.0 – 9.0	7.0 – 9.0	7.0 – 9.0
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015 – 1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025
Microalbumin (ALB)	10 – 30 mg/L	10 – 30mg/L	10 – 30 mg/L	80 – 150 mg/L	80 – 150 mg/L	80 – 150 mg/L
Creatinine (CRE)	10 – 100 mg/dL	0.9 – 8.8 mmol/L	10 – 100 mg/dL	100 – 300 mg/dL	8.8 – 26.5 mmol/L	100 – 300 mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal

Mission® *Expert* Urinalysis Reagent Strips Analyzer Reading with *Mission*® *Expert* U120/U500*

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–
Blood (ERY, Hb)	Negative	Negative	–	25 – 250 Ery/µl	25 – 250 Ery/µl	2+ – 5+
Bilirubin (BIL)	Negative	Negative	–	1– 6 mg/dL	17 – 100 µmol/L	1+ – 3+
Urobilinogen (URO)	0.2 mg/dL	3.5 µmol/L	–	4 – 12 mg/dL	70 – 200 µmol/L	2+ – 4+
Ketone Bodies (KET)	Negative	Negative	–	15 – 150 mg/dL	1.5 – 15.0 mmol/L	2+ – 4+
Glucose (GLU)	Negative	Negative	–	100 – 1000 mg/dL	5.5 – 56 mmol/L	2+ – 4+
Protein (PRO)	Negative	Negative	–	25 – 500 mg/dL	0.25 – 5.0 g/L	1+ – 4+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+
Leukocytes (LEU)	Negative	Negative	–	25 – 500 Leu/µl	25 – 500 Leu/µl	1+ – 3+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015 – 1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025
Microalbumin (ALB)	10 – 30 mg/L	10 – 30 mg/L	10 – 30 mg/L	80 – 150 mg/L	80 – 150 mg/L	80 – 150mg/L
Creatinine (CRE)	10 – 100 mg/dL	0.9 – 8.8 mmol/L	10 – 100 mg/dL	100 – 300 mg/dL	8.8 – 26.5 mmol/L	100 – 300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal

*The U120 QC set-up screen recognizes only arbitrary values

(LCD0187-05)

Mission®

Liquid Urine Control

Package Insert

REF U021-011	English

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 (36-46°F). Do not freeze.
- Controls are stable until the expiration date printed on the bottle label when stored at 2-8°C (36-46°F).
- All analytes are stable for 30 days at 15-30°C (59-86°F) or until the expiration date at 2-8°C (36-46°F) once opened and stored with the cap on tightly.

MATERIALS

Materials Provided

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

Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow all test materials to reach room temperature (15-30°C or 59-86°F) prior to testing.

1. 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.
2. 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.
3. Compare the reagent areas to the corresponding color blocks on the color chart 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.
4. Clean the dropper tip, and immediately replace the cap tightly.

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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

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by	EC REP	Authorized Representative
2°C 8°C	Store between 2-8°C	LOT	Lot Number	REF	Catalog #

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

CE

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150529004
Effective date: 2013-02-16

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.[8] 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

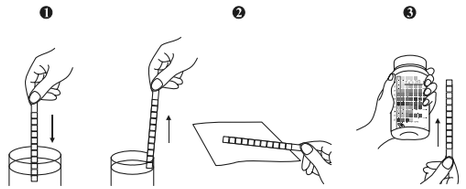
Materials Required But Not Provided

- 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.

1. 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.
2. 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.
3. 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 rifampen 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 cephalexin, 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]

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Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
EC REP	Authorized Representative				

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

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150310404
Effective date: 2011-03-14