



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Manufacturer:

ACON Laboratories, Inc.

5850 Oberlin Drive, #340
San Diego CA 92121
USA

**Product Category(ies): Blood glucose measuring systems for self testing
and self-testing devices for clinical chemistry,
hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1 104507 0003 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:V1_104507_0003_Rev.06)

Report no.:

SH22743EXT01

Valid from:

2022-05-04

Valid until:

2025-05-26

Date,

2022-05-04

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream,
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281),
On Call Sure Blood Glucose Monitoring System (OGM-211),
On Call Sure Sync Blood Glucose Monitoring System (OGM-212),
On Call Sure Blood Glucose Test Strips (OGS-211),
GIMA Blood Glucose Monitoring System,
GIMA Bluetooth Blood Glucose Monitoring System,
GIMA Blood Glucose Test Strips,
On Call GU Dual Blood Glucose & Uric Acid Monitoring



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

System (OGM-201),
On Call Blood Uric Acid Test Strips (OGS-201),
LH Ovulation Rapid Test Cassette (Urine),
Ovulation Rapid Test Midstream,
Ovulation & Pregnancy Test Combo Pack,
On Call Extra Voice Blood Glucose Monitoring System
(OGM-291),
Early Detection Pregnancy Test,
Digital Pregnancy Test,
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-
161),
Go-Keto Blood Ketone Test Strips (OGS-161),
Go-Keto Blood Glucose Test Strips,
On Call Extra GM Blood Glucose Monitoring System(OGM-
191),
On Call Extra GM Blood Glucose Test Strips (OGS-191),
On Call Plus GM Blood Glucose Monitoring System,
On Call Plus GM Blood Glucose Test Strips,
Go-Keto Urinalysis Reagent Strips

Facility(ies):

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

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

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana
B.C. CP, MEXICO

Declaration of Conformity

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

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

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:**

Mission ® Liquid Urine Control (U021-011, U021-021, U021-031)

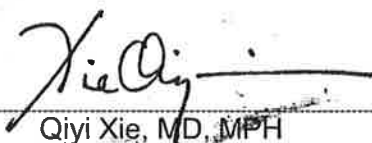
classified as Others in the directive 98/79/EC,

**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 11th day of December, 2019
in San Diego, CA, USA



Qi Yi Xie, MD, MPH
Senior Staff, Regulatory Affairs & 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.

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: June 2, 2022

Signature:



Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com

Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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



Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

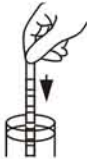
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

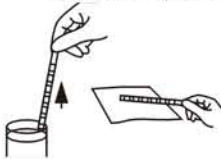
- Compatible for visual and analyzer reading
- More than 30 different combinations available

Multiple Packaging Options and Long Shelf Life

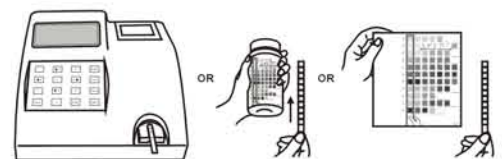
- Canister Packaging
 - Available in 25, 50, 100 and 150 strips per kit
 - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
 - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!*
 - Single-strip Pouch
 - Individually packaged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



Step 1: Immerse strip into urine



Step 2: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

Catalog No.	No. of Parameters	Type of Strip [♦]		Strips per Canister [◊]	Pouch Packaging [▲]	Reading Method			Analyzer-Read Strips: Standard (S) or Additional (A)	Parameters													
		For Visual Reading	For Analyzer Reading (U120/U500)			Visual	U120	U500		ASC	GLU	BIL	KET	SG	BLO	pH	PRO	URO	NIT	LEU	ALB	CRE	
U031-131	13	13C	NA	100 [■]	✓	✓	NA	NA	A	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-111	11	11A		100	✓	✓	✓	✓	S	*	*	*	*	*	*	*	*	*	*	*	*		
U031-101	10	10U		100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*		
		10A				✓	✓	✓	A	*	*	*	*	*	*	*	*	*	*	*			
		10C				✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*	*	
U031-091	9	9U		100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*			
U031-081	8	8U		100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*		
		8N				✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*		
		8S				✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*		
U031-071	7	7N		100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*			
U031-061	6	6N	6NE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*		
		6U	6UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
U031-051	5	5B	5BE	100	✓	✓	✓		A		*	*	*	*	*	*	*	*	*	*	*		
		5N	5NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		5S	5SE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		5U	5UE			✓	✓				*	*		*	*	*	*	*	*	*	*		
U031-041	4	4S	4SE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*		
		4B	4BE			✓	✓				*	*	*	*	*	*	*	*	*	*	*		
		4K	4KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		4G	4GE			✓	✓				*	*	*	*	*	*	*	*	*	*	*		
		4N	4NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		4P	4PE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
U031-031	3	3P	3PE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*		
		3K	3KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		3G	3GE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		3N	3NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
U031-021	2	2G	2GE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*		
		2K	2KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		2N	2NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		2B	2BE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		2U	2UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		2S	2SE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		2C	2CE	100 [■]	✓	✓	✓		*	*	*	*	*	*	*	*	*	*	*				
U031-011	1	1B	1BE	100	✓	✓	✓		A		*	*	*	*	*	*	*	*	*	*	*		
		1P	1PE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		1G	1GE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		1K	1KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		
		1R	1RE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*		

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

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

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



U120 Urine Analyzer



Accurate

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

Reliable

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

Convenient Operation

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

Easy Data Management

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

Unique Lockout Functions *new!*

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

Specifications

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

Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U120 Urine Analyzer	U111-101 [†]	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Quick Start Guide 1 Instruction Manual	42.0 cm x 41.5 cm x 31 cm; 5.0 kg 16.4" x 16.2" x 12.1"; 176.4 oz		1
U120 Urine Analyzer with Barcode Reader	U111-111 [†]	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Quick Start Guide 1 Instruction Manual	44.5 cm x 44.5 cm x 40.0 cm; 5.5 kg 17.5" x 17.5" x 15.7"; 194 oz		1
Barcode Reader	U221-111 [†]	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg 9.3" x 4.3" x 3.1"; 17.0 oz	63.0 cm x 37.0 cm x 30.0 cm; 12.0 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.36 kg 4.7" x 4.7" x 2.6"; 12.7 oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
U120 Data Transfer Kit	U221-131 [†]	1 Data Transfer Cable (RS232C)	1 Package Insert	12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	8

U500 Urine Analyzer



Accurate and Efficient

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

Easy to Operate

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

Convenient

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

Data Management Capability

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

Unique Lockout Functions Coming Soon!

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

Specifications

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

Ordering Information

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

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✓ CE Marked for sale in the European Community

† Cleared for US 510(k)



Mission[®]

Urine Controls

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

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



Global Diagnostics for Local Markets™

Mission® Urine Controls

Reliable

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

Quick and Convenient Testing

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

Two Types of Urine Controls Available

Liquid Urine Control

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

Dry Strip Urine Control

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



Specifications

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

Ordering Information

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

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

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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)

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

- Package Insert

Materials Required But Not Provided

- Timer

- Liquid Urine Control Level 1 and/or Level 2

- Strips

DIRECTIONS FOR USE

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

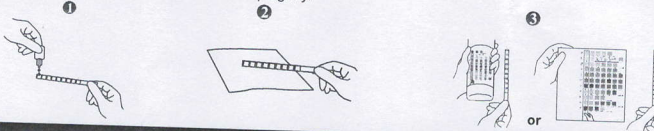
Note:

- Do not touch the tip of the urine control bottle to the reagent areas on the urinalysis reagent strip to avoid contamination.
- Dispose of the hanging drop of urine control before turning the urine control bottle upright.
- 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 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.

- 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

	Consult instructions for use		Tests per kit		Manufacturer
	For in vitro 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



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150529004
Effective date: 2013-02-16