Digitally signed by Dolgopol Iulian
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Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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.

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

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

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

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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TÜV®

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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

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

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

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

TÜV®

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.

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

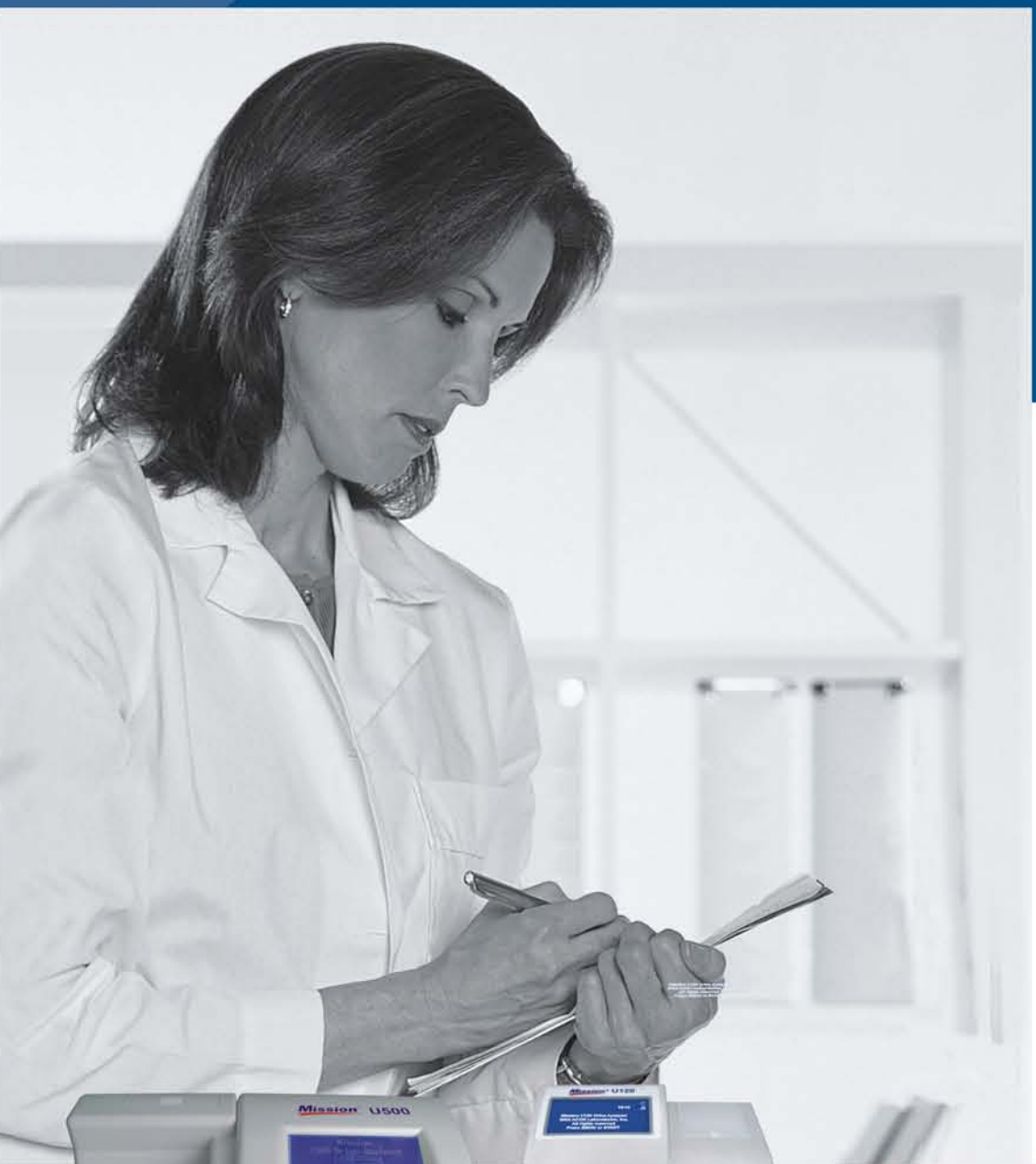
For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

ACON LABORATORIES, INC. S.A.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc.
jalvarenga@aconlabs.com
+1 858 875 8085

Mission® Urinalysis Reagent Strips and Urine Analyzers



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

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

ACON®

Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

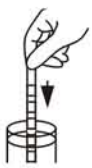
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

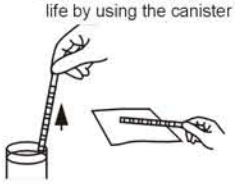
- Compatible for visual and analyzer reading
- More than 30 different combinations available

Multiple Packaging Options and Long Shelf Life

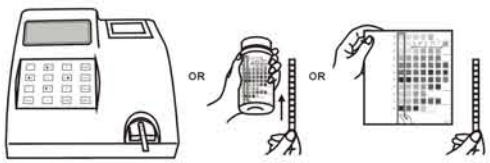
- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging ***New!***
  - Single-strip Pouch
    - Individually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



Step 1: Immerse strip into urine



Step 2: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

Catalog No.	No. of Parameters	Type of Strip♦		Strips per Canister◇	Pouch Packaging▲	Reading Method			Analyzer-Read Strips: Standard (S) or Additional (A)	Parameters												
		For Visual Reading	For Analyzer Reading (U120/U500)			Visual	U120	U500		ASC	GLU	BIL	KET	SG	BLO	pH	PRO	URO	NIT	LEU	ALB	CRE
U031-131	13	13C	NA	100■	✓	✓	NA	NA	A	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-111	11	11A		100	✓	✓	✓	✓	S	*	*	*	*	*	*	*	*	*	*	*		
U031-101	10	10U		100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*		
		10A				✓	✓	✓	A	*	*	*	*	*	*	*	*	*	*			
		10C		100■		✓	✓	✓	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	44.5cm x 44.5cm x 40.0cm; 5.5 kg 17.5" x 17.5" x 15.7"; 194 oz		1
Barcode Reader	U221-111√†	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	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
			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√†	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

√CE Marked for sale in the European Community CE

† Cleared for US 510(k)

U500 Urine Analyzer

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

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

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

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

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

Specifications

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

Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U500 Urine Analyzer	U211-101√	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual	51.0 cm x 42.0 cm x 38.5 cm; 7 kg 20.1" X 16.5" x 15.2"; 246.9 oz		1
U500 Urine Analyzer with Barcode Reader	U211-111√	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Instruction Manual	55.0 cm x 55.0 cm x 55.0cm; 9.2 kg 21.7" x 21.7" x 21.7"; 324.5 oz		1
Barcode Reader	U221-111√†	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm 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

We also offer other rapid diagnostic and medical products:

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1150449703

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

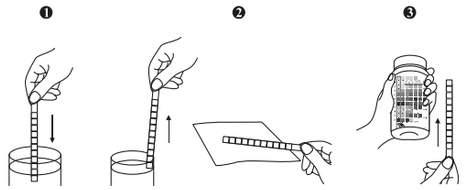
Materials Required But Not Provided

- 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

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®

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*

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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[New!] and CRE[New!]
- Control Level 2 provides positive results for LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB[New!] and CRE[New!] 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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1150531002

Liquid Urine Control

Package Insert

REF U021-011	**English**
REF U021-021	
REF U021-031	

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

INTENDED USE

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

PRECAUTIONS

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

REAGENTS

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

STORAGE AND STABILITY

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

MATERIALS

Materials Provided

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

Materials Required But Not Provided

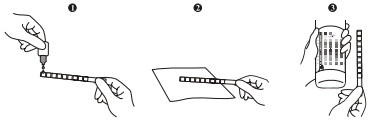
- Strips
- Timer

DIRECTIONS FOR USE

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

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 canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.
   Note:
   - Results may be read up to 2 minutes after the specified times.
   - Results may also be read using the *Mission*® and *Mission*® *Expert* Urine Analyzers. Refer to the Instruction Manual for details.
4. Clean the dropper tip, and immediately replace the cap tightly.



EXPECTED VALUES

The expected values listed on the following page should only be used for the specific lots printed. Expected values were obtained from replicate analysis. The urine control and urinalysis reagent strip lots can create slight differences in expected results. Different laboratory methods, instruments and reagents can create variations between laboratories and variations over time. Use the results provided as reference only. It is recommended that each laboratory establish its own parameters of precision.
Note: The color reactions of Urobilinogen and Bilirubin reagent areas on the urinalysis reagent strips may produce colors that are atypical when visually compared to the color blocks on the color chart.

LIMITATIONS

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

Index of Symbols

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

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

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150529002
Effective date: 2010-xx-xx

Atlas Medical

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH
Ludwig-Erhard-Ring 3,
15827Blankenfelde-Mahlow, Germany
Tel: +49 33 70 83 55 030
Email: amug@atlas-medical.com

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area
P. O. Box 204, Amman 11512, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Agent: San Medico
Republic of Moldova, city Chisina
+37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Maldova

Appointment Conditions:

1. This appointment is valid for 3 year from the above mentioned date.
2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer
General Manager
Haya Amawi

Atlas Medical
Quality Diagnostic Products

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

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GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2023 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2026 (included)**
Etabli le */ Issued on :* **October 9th, 2023**

DocuSigned by:
Béatrice LYS
EF33BDA9BA...
GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

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Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

2 sites / *2 sites*

DocuSigned by:
Beatrice Lys
FF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow, Germany.
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  Certificate N^0.: 36655 rev 1
  Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March.2021	09.03.2021		

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card,stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

Atlas Medical
Quality Diagnostic Products

Atlas D-Dimer Latex Kit

IVD *For In Vitro Diagnostic Use Only.*

Store at 2°C to 8°C.

INTENDED USE

A manual slide latex agglutination test for the qualitative and semi-quantitative detection of circulating derivatives of cross-linked fibrin degradation products (XL-FDP) in human citrated plasma to exclude Venous Thromboembolism (VTE) in patients suspected of Deep Vein Thrombosis (DVP) and Pulmonary Embolism (PE).

INTRODUCTION

During blood coagulation, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerize to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, but only degradation products from cross-linked fibrin contain D-Dimer. Therefore, cross-linked fibrin degradation products (XL-FDP) are a specific marker of fibrinolysis.

PRINCIPLE

Atlas D-Dimer Latex is a rapid agglutination assay utilizing latex beads coupled with a highly specific D-Dimer monoclonal antibody. XL-FDP present in a plasma sample bind to the coated latex beads, which results in visible agglutination occurring when the concentration of D-Dimer is above the threshold of detection of the assay.

MATERIALS

MATERIALS PROVIDED

- D-Dimer Latex Reagent: a 0.83% suspension of latex particles coated with murine anti-D-Dimer monoclonal antibody, 10mg/mL BSA and 0.1% sodium azide.
- D-Dimer Positive Control: a solution containing purified human D-Dimer fragment, 5mg/mL BSA and 0.1% sodium azide.
- D-Dimer Negative Control: a buffer solution containing 5mg/mL BSA and 0.1% sodium azide.
- Dilution Buffer
- Reaction slide
- Stirring Sticks
- Instructions for Use.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Precision pipettes and tips - 20 µL and 100 µL
- Plastic test tubes and rack
- Stopwatch or timing device
- Disposable gloves
- Tissue (for wiping dropper bottle tips)

PACKAGING CONTENT

REF **8.00.17.0.0025 (D-Dimer Latex 1x0.5mL, 2x0.4mL Controls, 1x10mL Glycine Buffer)**

REF **8.00.17.0.0050 (D-Dimer Latex 1x1mL, 2x0.5mL Controls, 1x10mL Glycine Buffer)**

REF **8.00.17.0.0100 (D-Dimer Latex 1x2mL, 2x1mL Controls, 2x10mL Glycine Buffer)**

REF **8.00.17.2.0100 (D-Dimer Latex 1x2mL, 2x0.5mL Controls, 2x10mL Glycine Buffer)**

REF **8.00.17.0.0200 (D-Dimer Latex 1x4mL, 2x2mL Controls, 1x40mL Glycine Buffer)**

PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- Harmful if swallowed. Avoid contact with skin and eyes. Do not empty into drains.
- Wear suitable protective clothing.
- CAUTION: All reagents in Atlas D-Dimer Latex Kit contain sodium azide (0.1%) as preservative. Do not ingest or allow to contact skin or mucous membranes. Sodium azide may form explosive azides in metal plumbing. Use proper disposal procedures.
- CAUTION: The Positive Control in Atlas D-Dimer Latex Kit contain components of human origin. Each individual blood donation intended for the production of this reagent is tested for HBsAg, anti-HCV, anti-HIV1 and anti-HIV2. Only donations with negative findings are employed. As complete absence of infectious agents can never be assured, all materials derived from human blood should be treated as potentially infectious and handled with due care following the precautions recommended for biohazardous material.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Do not use these reagents if the label is not available or damaged.
- Test materials and samples should be discarded properly in a biohazard container.

STORAGE AND STABILITY

- Store at 2°C to 8°C.
- DO NOT FREEZE.
- Stability: Refer to outer package and vial labels for expiration date.
- Opened vials are stable until specified expiry date printed on vial label when stored refrigerated (2 - 8°C).
- Indication of Reagent Deterioration
  Reagent deterioration is indicated by failure of the Latex Reagent to agglutinate with the Positive Control, agglutination with the Negative Control, or evidence of microbial contamination.

SPECIMEN COLLECTION AND PREPARATION

- Use fresh plasma prepared by centrifugation of whole blood collected using tube contain sodium citrate anticoagulant. (The use of EDTA and heparin will result in an increased level of false positive reaction).
- The test works best on fresh plasma samples. If testing cannot be done immediately, plasma samples should be stored at -20ºC up to 2 weeks.
- Specimen may be tested directly for the presence of XL-FDP. Defibrination of the plasma is not recommended.
- Frozen specimen should be rapidly thawed at 37 °C and centrifuged before testing.

PROCEDURE

- Equilibrate reagents to room temperature (20°C to 25°C) before use.
- Latex Reagent should be mixed by inversion immediately prior to use.

Qualitative Method

1. Bring reagents and specimens to room temperature before use.
2. Place 20 µL of the reagent within a field on the reaction slide.
3. Accurately pipette 20 µL of undiluted plasma or of control solution next to the drop of Latex Reagent.
4. Mix the Latex Reagent and sample with a stirrer until the Latex is uniformly distributed.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for three minutes.
6. At exactly 3 minutes, check for agglutination under a strong light source.

NOTE

If test reading is delayed beyond 3 minutes, the latex suspension may dry out **giving a false agglutination pattern. If this is suspected, the specimen must be retested.**

Semi quantitative Method

1. Prepare serial dilutions of the test plasma with Buffer as follows:
1:2 dilution 100 µL plasma plus 100 µL Buffer solution
1:4 dilution 100 µL 1:2 dilution plus 100 µL Buffer solution
1:8 dilution 100 µL 1:4 dilution plus 100 µL Buffer solution
2. Test each dilution as described in the qualitative method.

QUALITY CONTROL

- It is recommended that both Positive and Negative Controls be included in each batch of tests to ensure proper functioning of the system. Control solutions should be tested by the same procedures as patient samples.
- D-Dimer Positive Control consists of a solution of human D-Dimer at a level of approximately ≥ 0.80 mg/L (≥ 800ng/mL).

RESULTS

A. Qualitative Assay

For the qualitative assay protocol, the following pattern of results should be obtained:

Undiluted Plasma D-Dimer (XL-FDP) concentration

- Less than 0.15 mg/L (150ng/mL): Negative result
- Greater than 0.15 mg/L (150ng/mL): Positive result

B. Semiquantitative Assay

Approximate levels of XL-FDP, containing the D-Dimer domain, for specimen dilutions are shown in Table 1. As with all semiquantitative tests, some variability in dose-response can be expected.

Approximate Range of D-Dimer (XL-FDP) mg/L (ng/ml)	Sample Dilution			
	Undil.	1:2	1:4	1:8
< 0.2 (< 200)	-	-	-	-
0.2 – 0.4 (200 – 400)	+	-	-	-
0.4 – 0.8 (400 – 800)	+	+	-	-
0.8 – 1.6 (800 – 1600)	+	+	+	-
1.6 – 3.2* (1600 – 3200*)	+	+	+	+

"+" = agglutination, "-" = no agglutination

* Levels of XL-FDP greater than 3.20 mg/L (3200 ng/mL) can be estimated by further dilutions beyond 1:8.

EXPECTED VALUES

A positive result, indicating active fibrinolysis, should be obtained with D-Dimer Latex Test when XL-FDP (D-Dimer) levels are at or greater than approximately 0.20 mg/L (200ng/mL). Plasma specimens from normal subjects are expected to give negative results because their plasma XL-FDP concentrations are typically less than 0.20 mg/L (200ng/mL). Due to many variables that may affect results, each laboratory should establish its own normal range.

Elevated levels of XL-FDP (containing the D-Dimer domain) have been demonstrated in patients by a combination of immunoprecipitation and gel electrophoresis techniques. Monoclonal antibodies allow the specific detection of the D-Dimer domain. Monoclonal antibody based D-Dimer assay is of diagnostic value in disseminated intravascular coagulation (DIC) and acute vascular diseases, including pulmonary embolism (PE) and deep venous thrombosis (DVT), conditions that are difficult to detect reliably by clinical examination.

The amount of XL-FDP detected in a specimen will depend on several interrelated factors in vivo, such as the severity of the thrombotic episode, the rate of cross linked fibrin formation, and the time elapsed after the thrombotic event until blood is drawn from the patient.

Elevated levels of XL-FDP as an indication of reactive fibrinolysis have also been reported in surgery, trauma, sickle cell disease, liver disease, severe infection, sepsis, inflammation, and malignancy. D-Dimer levels also rise during normal pregnancy but very high levels are associated with complications.

LIMITATIONS

Clinical diagnosis should not be based on the result of D-Dimer Latex alone. Clinical signs and other relevant test information should be included in the diagnostic decision.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Diagnostic Sensitivity: 100.00% (95% CI (97.34% to 100.00%))
- Diagnostic Specificity: 94.38% (95% CI (89.91% to 97.27%)).
- Positive Predictive Value: 93.20% (95% CI (88.24% to 96.16%)).
- Negative Predictive Value : 100%
- Accuracy: 96.83% (95% CI (94.24% to 98.47%)).
- Intra-assay (within run) reproducibility was determined for 10 replicates of 3 plasma samples that contained different levels of XL-FDP. The results were equivalent for all replicates.
- Inter-assay (run-to-run) reproducibility was determined using 10 plasma samples with XL-FDP titers ranging from 1 to 16. In 10 runs, the replicates of these specimens did not vary by more than one titer.
- In an anticoagulant study of 50 parallel citrated, EDTA and heparin plasma samples, the test result showed that the following:
  - Plasma prepared from whole blood anticoagulated with sodium citrate is recommended.
  - The use of EDTA and heparin sodium will result in an increased level of false positive reaction.
- No assay interference was demonstrated with Atlas D-Dimer Latex with spiked specimens containing potential interfering substances at the following concentrations:
  - Bilirubin 0.2 mg/mL
  - Hemoglobin 5.0 mg/mL
  - Lipids (triglycerides) 30 mg/mL
  - Protein (gamma globulin) 0.06 g/mL

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ATLAS Medical GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

PPI1473A01
Rev D (06.05.2023)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control