

## 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: January 3, 2023

Signature:



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



# 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](http://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.

## 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



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





## Declaration of Conformity

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

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

Device Name	REF Number	Model Number
Mission® Liquid Urine Control	U021-011	n/a
SPINREACT Liquid Urine Control	U021-013A	n/a
Insight® Liquid Urine Control	U021-015	n/a
Mission® Liquid Diptube Urine Control	U021-071	n/a
Insight® Liquid Diptube Urine Control	U021-075	n/a

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

**meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic  
medical devices which apply to it**

**The self-declaration is according to Annex III  
(excluding Section 6) of the Directive.**

Authorized Representative:  
Medical Device Safety Service GmbH  
Schiffgraben 41  
30175 Hannover, Germany

Signed this 22 day of October, 2021  
in San Diego, CA, USA



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



# Declaration of Conformity

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

Device Name	REF Number
Mission® U120 Smart Urine Analyzer	U117-101, U117-111
Mission® U120 Smart Urine Analyzer Data Transfer Kit	U127-131
Mission® Urine Analyzer Barcode Reader	U221-111
Mission® Printer Paper Rolls	U121-101
Insight® U120 Smart Urine Analyzer	U117-105, U117-115
Insight® U120 Smart Urine Analyzer Data Transfer Kit	U127-135
Insight® Barcode Reader	U221-115
Insight® Printer Paper Rolls	U121-105
Urispin U120 Smart Urine Analyzer	5004003

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

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

and

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

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

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

## **This declaration is based on:**

**Manufacturer's Name:** ACON Laboratories, Inc.

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

**Manufacturer's SRN:** US-MF-000023913

**Authorized Representative Name:** Medical Device Safety Service GmbH

**Authorized Representative Address:** Schiffgraben 41, 30175 Hannover, Germany

**Basic UDI-DI:** 682607999999004149

**Intended Purpose of device:** The U120 Smart Urine Analyzer is intended for use in conjunction with the Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in human urine: Albumin, Creatinine, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, pH, Blood, Protein, Urobilinogen, Leukocytes, Ascorbic Acid and Calcium, as well as the qualitative detection of Nitrite. The instrument is intended for professional, *in vitro* diagnostic use only. The measurement 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.

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



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

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





**ACON Laboratories, Inc.**

10125 Mesa Rim Road. • San Diego, CA 92121 • USA  
Tel: (858) 875-8000 • Fax: (858) 875-8099 • E-mail: [info@aconlabs.com](mailto:info@aconlabs.com)

November 11<sup>th</sup> 2016

**CERTIFICATION LETTER**

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer  
Mission® U120 Ultra Urine Analyzer  
Mission® U500 Urine Analyzer  
Mission® PT/INR Coagulation Monitoring System  
Mission® Cholesterol Monitoring System  
Mission® Ultra Cholesterol Monitoring System  
Mission® HB Hemoglobin Testing System  
Mission® Plus HB Hemoglobin Testing System  
OnCall® Glucose Meter

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

Sincerely

A handwritten signature in black ink, appearing to read "Jassy Alvarenga", is written over a red circular stamp.



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

[jalvarenga@aconlabs.com](mailto:jalvarenga@aconlabs.com)

+1 858 875 8085



# Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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



Global Diagnostics for Local Markets™

# Urinalysis Reagent Strips

## Simple and Accurate

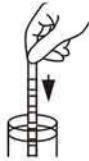
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

## Flexible

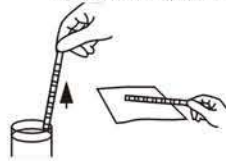
- Compatible for visual and analyzer reading
- More than 30 different combinations available

## Multiple Packaging Options and Long Shelf Life

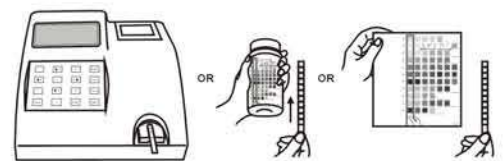
- Canister Packaging**
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!***
  - Single-strip Pouch**
    - Individually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



Step 1: Immerse strip into urine



Step 2: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

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

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

° Also available in canisters of 25, 50 and 150 strips.

▲ Not available in canisters of 150 strips

▲ Single-strip Pouch available in 1, 3, 6 and 20 strip kit

Canister Refill Kit, with 25 strips per pouch or canister, available in 3-pouch and 1- canister kit, or 4-pouch kit

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





# U120 Urine Analyzer



## Accurate

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

## Reliable

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

## Convenient Operation

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

## Easy Data Management

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

## Unique Lockout Functions *new!*

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

## Specifications

Feature	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	Single Test Option: 60 tests/hour 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 <sup>†</sup>	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 <sup>†</sup>	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 <sup>†</sup>	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg 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 <sup>†</sup>	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

**We also offer other rapid diagnostic and medical products:**

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

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



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# **Mission<sup>®</sup>**

## **Urine Controls**

Simply validate  
visual and analyzer  
urinalysis with  
**Mission<sup>®</sup>** Liquid and  
Dry Strip Urine  
Controls!

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



**ACON<sup>®</sup>**

Global Diagnostics for Local Markets™

# Mission® Urine Controls

## Reliable

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

## Quick and Convenient Testing

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

## Two Types of Urine Controls Available

### Liquid Urine Control

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

### Dry Strip Urine Control

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



## Specifications

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

## Ordering Information

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

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

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Blood Glucose Monitoring Systems, Clinical Chemistry including Urinalysis, Immunoassay EIA/ELISA and more.

**Contact us for worldwide distribution and custom manufacturing (OEM) opportunities**





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## Capitolul 1. Introducere

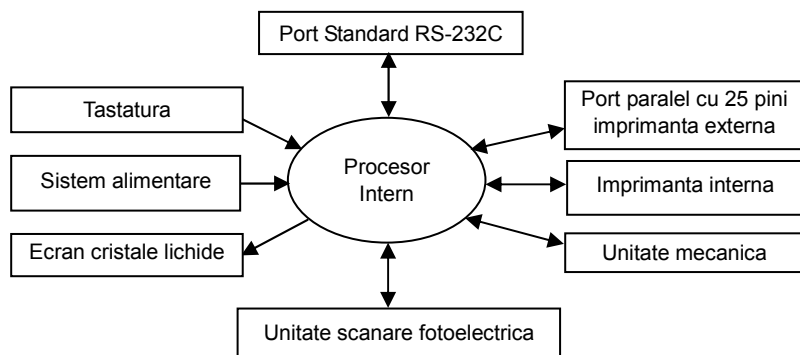
Analizorul de urini *Mission*<sup>™</sup> U120 este un fotometru care analizeaza intensitatea si culoarea reflectate din zona de reactie a stripului. Fara un analizor, operatorul trebuie sa compare zona de reactie a stripului cu un tabel de culori folosind ochiul liber. De aceea, determinarea vizuala a analizei de urina necesita timp indelungat de lucru. In plus, testarea vizuala tinde spre inexactitate datorata interpretarii gresite si sursei variabile de lumina. Pentru a minimaliza variabilitatea asociata cu testarea vizuala, analizorul *Mission*<sup>™</sup> U120 este creat special pentru a imbunatati eficacitatea si acuratetea analizei de urina avand capacitati de ultima generatie de management al datelor si de transferare a lor.

Analizorul *Mission*<sup>™</sup> U120 utilizeaza optica moderna, electronice sigure si un soft usor de operat. Folosind o dioda emitatoare de lumina (LED) ca sursa de lumina si o fotodioda ca senzor de lumina, sistemul optic avansat furnizeaza operatorului rezultate exacte. Electronicele interne sunt configurate intr-un circuit modular integrat creat sa minimizeze interferentele electromagnetice si sa ofere siguranta. Software-ul este creat sa mareasca functionalitatea analizorului cu o instruire minima. Analizorul este de asemenea capabil sa ajusteze rezultatele densitatii bazat pe pH-ul urinar masurat pentru a compensa variatia concentratiei ionilor. In plus, analizorul este conceput cu calibrare automata si capacitate de auto-control pentru interpretari exacte. Impreuna, aceste caracteristici furnizeaza rezultate sigure si o eficienta imbunatatita in testarea urinelor.

## Capitolul 2. Componentele analizorului

### Schema analizorului

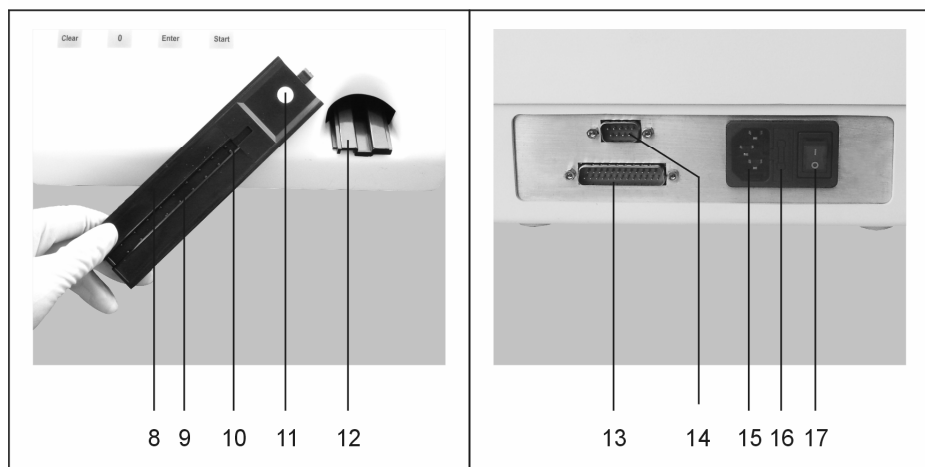
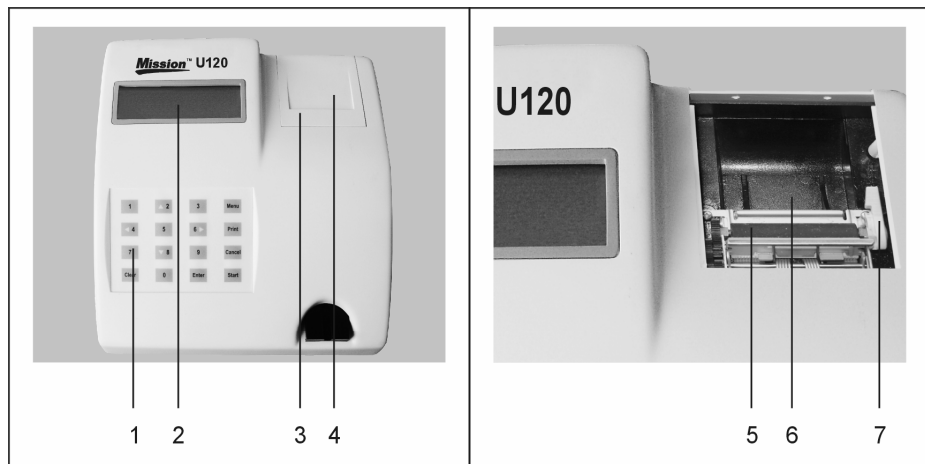
Analizorul este compus dintr-un procesor intern cu memorie, unitate mecanica, ecran cu cristale lichide, unitate de scanare fotoelectrica, sistem de alimentare, tastatura, port pentru imprimanta externa cu 25 de pini, imprimanta interna si port standard RS-232C.



Componenta de baza a analizorului este procesorul intern, care este capabil sa trimita, sa primeasca, sa proceseze si sa inregistreze semnale de la diferitele componente aratate mai sus. Tastatura permite operatorului sa controleze analizorul si sa acceseze informatia stocata in baza de date. Ecranul cu cristale lichide permite operatorului sa vizualizeze numeroase imagini si sistemul de alimentare furnizeaza puterea necesara pentru ca analizorul sa functioneze. Unitatea de scanare fotoelectrica este creata sa lumineze stripul si analizeaza lumina reflectata. Unitatea mecanica muta suportul stripului in pozitia in care unitatea de scanare fotoelectrica analizeaza stripul. Imprimanta interna printeaza rezultatele pentru inregistrările operatorului. Portul RS-232C si portul cu 25 de pini permit analizorului sa comunice cu computer si imprimanta.

## Lista componentelor

- |                                            |                                                  |
|--------------------------------------------|--------------------------------------------------|
| 1. Tastatura                               | 10. Opritor suport stripuri                      |
| 2. Ecran cu cristale lichide               | 11. Cerc alb pentru calibrare                    |
| 3. Capac imprimanta                        | 12. Fixator suport stripuri                      |
| 4. Fanta de acces pentru hartie imprimanta | 13. Port pentru imprimanta externa cu 25 de pini |
| 5. Rola imprimanta                         | 14. Port standard RS232C                         |
| 6. Container hartie imprimanta             | 15. Priza                                        |
| 7. Parghie imprimanta                      | 16. Sigurante                                    |
| 8. Suport strip                            | 17. Intrerupator                                 |
| 9. Canal suport stripuri                   |                                                  |



## Capitolul 3. Setari

### Navigare in meniu

Urmăriti instructiunile de mai jos pentru a naviga in meniul analizorului.

### Ecranul principal

Ecranul principal cum e aratat mai jos, este afisat dupa terminarea operatiunii de autocontrol automat cand analizorul este pornit.

Nota: Va puteti intoarce la ecranul principal in orice moment folosind sagetile de pe tastatura si selectand "Exit" din orice alt ecran sau apasand tasta Cancel din fereastra "Place a strip on the holder".



- Data, ora, modelul si versiunea sunt indicate pe ecranul principal.
- Cele trei cercuri din partea dreapta a ecranului indica statutul analizorului: Mod de lucru single sau continuu (cercul de sus), Printare automata sau manuala (cercul din mijloc) si Prezenta sau absenta hartiei imprimante (cercul de jos).

Positie	Funcție	Simbol pe ecran
Cercul de sus	Mod de lucru Continuu	●
	Mod de lucru Single	○
Cercul din mijloc	Imprimare automata	●
	Imprimare manuala	○
Cercul de jos	Hartie imprimanta prezenta	●
	Hartie imprimanta absenta	Luminare intermitenta ●

### Meniul principal

- Din ecranul principal sau din fereastra "Place a strip on the holder": Apasati tasta Menu pentru a naviga in fereastra meniului principal, aratat mai jos.
- Din orice alt ecran: Folositi sagetile si selectati "Exit" pentru a naviga in meniul principal.



Options	PRT Setup	<input type="radio"/>
Database	Self Test	<input checked="" type="radio"/>
Unit	➔ Exit	<input checked="" type="radio"/>

#### Meniul "Options Menu"

- Folositi sagetile pentru a selecta "Options" din meniul principal, apoi apasati tasta Enter pentru a naviga in meniul "Options Menu", aratat mai jos.

Options Menu		<input type="radio"/>
CLOCK		<input checked="" type="radio"/>
LANGUAGE:	English	<input checked="" type="radio"/>
TYPE OF STRIP:	A08	<input checked="" type="radio"/>
CLINICAL NUMBER		
CONTINUOUS TEST	Off	
➔ EXIT		

#### Meniul "Database Menu"

- Folositi sagetile pentru a selecta "Database" din meniul principal, apoi apasati tasta Enter pentru a naviga in meniul "Database Menu", aratat mai jos.

Database Menu		<input type="radio"/>
➔ LOCATE		<input checked="" type="radio"/>
CURRENT RECORD		<input checked="" type="radio"/>
PREVIOUS RECORD		
NEXT RECORD		
EXIT		

#### Meniul "Unit"

- Folositi sagetile pentru a selecta "Unit" din meniul principal, apoi apasati tasta Enter pentru a naviga in meniul "Unit", aratat mai jos.

Unit: SI		<input type="radio"/>
		<input checked="" type="radio"/>
➔ Exit		<input checked="" type="radio"/>

### Meniul "Printer Setup" ("PRT Setup")

- Folositi sagetile pentru a selecta "PRT Setup" din meniul principal, apoi apasati tasta Enter pentru a naviga in meniul "Printer Setup", aratat mai jos.

Printer Setup

PRINTER SELECT: Internal

PRINTER MODE: Normal

AUTOPRINT: On

➔ EXIT

●

●

### Meniul "Self Test Results"

- Folositi sagetile pentru a selecta "Self Test" din meniul principal, apoi apasati tasta Enter pentru a naviga in meniul "Self Test Results", aratat mai jos.

Self Test Results

MAIN CONTROL UNIT

OPTICAL SENSOR

TEST ACCURACY

MECHANIC UNIT

EXCEED LIGHT

P a s s e d

P a s s e d

P a s s e d

P a s s e d

P a s s e d

●

●

### Scurtaturi

Folositi urmatoarele scurtaturi de tastatura din meniul principal pentru a schimba mai rapid setarile analizorului.

Scurtatura	Funcție	Simbol pe ecran
1	Mod de lucru Continuu	●
	Mod de lucru Single	○
3	Imprimare automata	●
	Imprimare manuala	○
5	Numar clinic	
7	Localizare rezultat	
9	Initializare auto-control	

### Setarea analizorului

Folositi instructiunile de mai jos pentru a seta imprimanta, unitatile, ora, limba, numarul clinic, tipul stripului si modul de lucru.

#### Pasul 1. Setarea imprimantei

Folositi Printer Setup a selecta optiunile de printare.

##### Incarcarea hartiei

Folositi rola de hartie disponibila pentru a incarca imprimanta internă.

- Indepartati capacul imprimantei apasand in jos partea de jos a capacului si ridicand partea de sus.
- Indepartati capacul imprimantei apasand in jos partea de jos a capacului si ridicand partea de sus.

3. Trageți parghia verde către suportul de stripuri pentru a permite hârtiei să fie alimentată direct.
4. Alimentați cu hârtie pe sub rola imprimantei și apoi trageți hârtia în sus așa cum e arătat mai jos. Lasăți cam 10 cm de hârtie deasupra rolei imprimantei.
5. Întoarceți parghia în poziția originală.
6. Strecurați hârtia prin fanta de acces a hârtiei imprimantei.
7. Așezați capacul imprimantei în poziția originală și apăsați-l ferm.



### **Selectare setarilor imprimantei**

*Schimbați setările imprimantei pentru a inversa imprimanta externă cu internă, caractere normale cu marite și printare manuală cu automată.*

#### **Imprimanta externă sau internă**

*Selectați imprimanta externă sau internă.*

1. Apăsați săgeata în sus (↑) pentru aselecta "PRT Setup" din meniul principal, apoi apăsați tasta Enter.  
Nota: Trimitere la **Meniul principal** de la pagina 5 pentru a naviga în meniul principal.
2. Apăsați săgeata în sus (↑) pentru a selecta "PRINTER SELECT". Setarea curentă va fi afișată imediat după setarea "PRINTER SELECT".
3. Apăsați tasta Enter pentru a selecta imprimanta "Internal" sau "External".  
Nota: Imprimanta internă este incorporată în analizor. O imprimantă externă poate fi conectată cu un cablu prin portul pentru imprimantă din spatele analizorului.

#### **Caractere normale sau marite**

*Selectați caractere normale sau marite.*

1. Folosiți săgeata în jos (↓) pentru a selecta "PRINTER MODE" din meniul "Printer Setup". Setarea curentă va fi afișată imediat după setarea "PRINTER MODE".  
Nota: Trimitere la **Setare imprimantă** la pagina 7 pentru a naviga în meniul "Printer Setup".
2. Apăsați tasta Enter pentru a selecta caractere "Normal" sau "Expand".  
Nota: Selectați "Normal" pentru a economisi hârtia imprimantei. Când "Expand" este selectat, hârtia este consumată mult mai repede datorită caracterelor marite.

## Printare manuala sau automata

*Selectati printare manuala sau automata.*

1. Apasati sageata in jos (↓) pentru a selecta "AUTOPRINT" din meniul "Printer Setup". Setarea curenta va fi afisata imediat dupa setarea "AUTOPRINT".

Nota: Trimitere la **Setare imprimanta** la pagina 7 pentru a naviga in meniul "Printer Setup".

2. Apasati tasta Enter pentru a selecta "On" sau "Off".

Nota:

- Mod de lucru Single/Mod de lucru Continuu: Daca "On" este selectat, fiecare rezultat va fi printat automat.
- Mod de lucru Single: Daca "Off" este selectat, operatorul trebuie sa apese tasta Print pentru fiecare rezultat care va fi printat.

3. Apasati sageata in jos (↓) pentru a selecta "EXIT" si apoi apasati tasta Enter pentru a reveni la meniul principal.

## Pasul 2. Setarea unitatilor

*Selectati sistemul international (SI) sau unitatile conventionale.*

1. Apasati sageata stanga (←) pentru a selecta "Unit" din meniul principal, apoi apasati tasta Enter.

Nota: Trimitere la **Meniul principal** de la pagina 5 pentru a naviga in meniul principal.

2. Apasati sageata sus (↑) pentru a selecta "Unit" apoi apasati tasta Enter pentru a selecta fie sistemul international (SI), fie unitatile conventionale.

Nota: Rezultate arbitrare vor fi printate automat indiferent de unitatea selectata.

3. Apasati sageata jos (↓) pentru a selecta "Exit" apoi apasati tasta Enter pentru a reveni la meniul principal.

## Pasul 3. Setarea ceasului

*Setati data si ora.*

1. Apasati sageata sus (↑) pentru a selecta "Options" din meniul principal, apoi apasati tasta Enter pentru a naviga in meniul "Options Menu".

Nota: Trimitere la **Meniul principal** de la pagina 5 pentru a naviga in meniul principal.

2. Apasati sageata sus (↑) pentru a selecta "CLOCK" apoi apasati tasta Enter pentru a vedea ecranul cum este aratat mai jos.

Please input time:

0-00-00 00:00:00

An (00) Luna (00) Zi (00) Ora (0-24) Minute (0-60) Secunde (0-60)

3. Folositi tastele cu numere pentru a introduce ora si data curenta asa cum este aratat in exemplul urmator: 05-08-12 13:30:00 (indicand 12 august 2005, 1:30PM). Daca informatia este introdusa incorect, apasati tasta Clear

pentru a putea reintroduce informatia. Apoi apasati tasta Enter dupa ce data si ora au fost introduse corect. Noua data si ora vor fi afisate pe ecranul principal.

Nota: Pentru a anula schimbarile, apasati tasta Cancel pentru a pastra setarea curenta.

4. Continuati cu setarea analizorului, sau apasati tasta Enter pentru a reveni la meniul principal.

#### **Pasul 4. Setarea limbii**

*Selectati limba engleza sau spaniol pentru a fi afisata pe ecran.*

1. Apasati sageata sus (↑) pentru a selecta "LANGUAGE" din meniul "Options Menu". Setarea curenta va fi afisata imediat dupa setarea "Language".

Nota: Trimitere la "**Options Menu**" de la pagina 6 pentru a naviga in meniul "Options Menu".

2. Apasati tasta Enter pentru a selecta limba "English" sau "Spanish".
3. Continuati cu setarea analizorului, sau apasati tasta Enter pentru a reveni la meniul principal.

#### **Pasul 5. Selectarea "Type of Strip"**

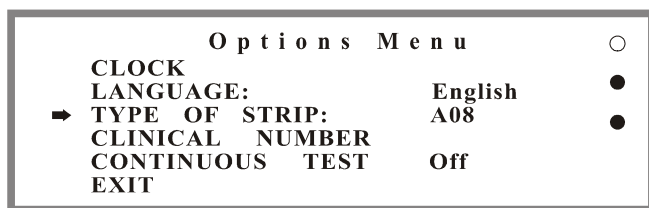
*Selectati tipul de strip care va fi testat.*

1. Apasati sageata jos (↓) pentru a selecta "TYPE OF STRIP" din meniul "Options Menu". Tipul curent de strip va fi afisat imediat dupa setarea "TYPE OF STRIP".

Nota: Trimitere la "**Options Menu**" de la pagina 6 pentru a naviga in meniul "Options Menu".

2. Apasati tasta Enter pentru a selecta "A08" pentru 8 parametri, "A09" pentru 9 parametri, "A10" pentru 10 parametri sau "A11" pentru 11 parametri. Trimitere la **Stripuri compatibile** de la pagina 23 pentru o lista detaliata.

**Nota: Asigurati-va ca tipul de strip selectat corespunde cu stripul care va fi folosit. Folosirea oricarui alt strip poate cauza rezultate incorecte.**



3. Continuati cu setarea analizorului, sau apasati sageata jos (↓) pentru a selecta "EXIT" apoi apasati tasta Enter pentru a reveni la meniul principal.

#### **Pasul 6. Setarea numarului clinic**

*Stabiliti numarul clinic pentru rezultatele probelor inregistrate.*

1. Apasati sageata jos (↓) pentru a selecta "CLINICAL NUMBER" din meniul "Options Menu".

Nota: Trimitere la "**Options Menu**" de la pagina 6 pentru a naviga in meniul "Options Menu".

2. Apasati tasta Enter pentru a afisa "Old number". Setarea standard este 000001.
3. Folositi taste cu numere pentru a introduce "New number" folosind 1-6 cifre.

Nota:

- Cel mai mare numar clinic este 999999. Dupa ce numarul clinic atinge 999999, revine la 000000.
- Daca este introdus un numar clinic incorect, apasati tasta Clear pentru a reintroduce informatia.
- Daca numarul clinic aratat ca "Old number" nu trebuie schimbat, apasati tasta Cancel.

**Avertisment:** Introducand un numar nou este posibila stergerea datelor existente daca numerele clinice se suprapun.

4. Apasati tasta Enter pentru a reveni la meniul "Options Menu".
5. Continuati cu setarea analizorului, sau apasati sageata jos (↓) pentru a selecta "EXIT" apoi apasati tasta Enter pentru a reveni la meniul principal.

## **Pasul 7. Selectarea modului de lucru single sau continuu**

*Selectati modul de lucru single pentru un flux redus de analize sau modul de lucru continuu pentru un flux marit de analize.*

### **Descrierea modului de lucru single si modului de lucru continuu**

- Modul de lucru single: Modul de lucru continuu este in pozitia "Off". Acest mod este recomandat pentru analizarea unui singur strip o data. Fluxul pentru modul de lucru single este 40 teste/ora.
- Modul de lucru continuu: Modul de lucru continuu este in pozitia "On". Acest mod este recomandat pentru analizarea continua a stripurilor unul dupa altul. Fluxul pentru modul de lucru continuu este de 120 teste/ora.

### **Selectarea modului de lucru single sau modului de lucru continuu**

1. Apasati sageata sus (↑) pentru a selecta modul "CONTINUOUS TEST" din meniul "Options Menu". Modul curent de lucru va fi afisat imediat dupa setarea modului "CONTINUOUS TEST".

Nota: Trimitere la "**Options Menu**" de la pagina 6 pentru a naviga in meniul "Options Menu".

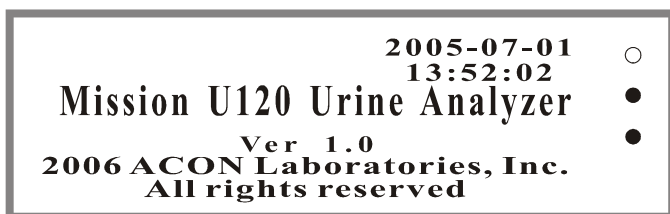
2. Apasati tasta Enter pentru a selecta pozitia "On" pentru modul de lucru continuu sau pozitia "Off" pentru modul de lucru single.
3. Apasati tasta Start pentru a incepe testarea.

## Capitolul 4. Instructiuni de operare

### Pasul 1. Pornirea analizorului pentru initierea auto-controlului

Urmăriti auto-controlul automat cand analizorul este deschis pentru a va asigura ca unitatea functioneaza corect.

1. Apasati intrerupatorul. Auto-controlul va incepe automat prin miscarea suportului pentru stripuri in afara si inapoi.
2. Verificati rezultatele auto-controlului:
  - Daca auto-controlul automat este reusit, ecranul principal va fi aratat ca mai jos indicand ca analizorul functioneaza corect.



- Daca auto-controlul automat nu este reusit, o fereastră "Failed" va fi afisata ca mai jos indicand sursa erorii. Trimitere la **Tabelul cu defectiuni** de la pagina 22 pentru a corecta eroarea.



### Pasul 2. Selectarea setarilor analizorului si pregatirea materialelor

Selectati "Type of Strip", "Continuous Test" modul sau "Single Test" modul, si "Clinical Number" pentru a particulariza setarea analizorului.

1. Apasati tasta Menu pentru a particulariza setarile incluzand "Type of Strip", "Continuous Test" modul sau "Single Test" modul, si "Clinical Number" asa cum este necesar. Sau apasati tasta Start pentru a folosi setarea curenta.  
Nota: Trimitere la **Setarea analizorului** de la pagina 7 pentru a particulariza setarile. Setarile standard pentru prima operare sunt setate de producator. Dupa prima folosire, fiecare din schimbarile facute la setari vor fi salvate si folosite pentru operatiile viitoare.
2. Lasati stripul, proba de urina, si/sau controalele sa ajunga la temperatura camerei de 15-30°C (59-86°F) inainte de testare.  
**Nota:** Folositi numai stripuri din aceeași gama cu analizorul pentru a asigura o functionare corecta si rezultate precise.
3. Scoateti stripurile din cutie si folositi-le cat mai curand posibil. Inchideti cutia imediatdupa scoaterea numarului necesar de stripuri.

### Pasul 3. Efectuarea testului si obtinerea rezultatelor

Introduceti stripul si obtineti rezultatele folosind modul de lucru single sau modul de lucru continuu.

#### Masurarea in modul de lucru single

Folositi modul de lucru single pentru a analiza probele de urina una o data. Trimitere la **Selectarea modului de lucru single sau modului de lucru continuu** de la pagina 11 pentru instructiuni in selectarea modului de lucru single.

1. Apasati tasta Start pentru a intinde suportul pentru stripuri. Fereastra "Place a strip on the holder" va fi afisata cum este aratat mai jos.

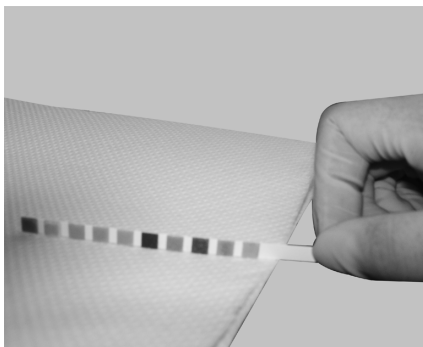


2. Apasati tasta Start si asteptati triplul bip pentru a incepe introducerea stripului. Nota: O data ce tasta Start este apasata, cronometrul din dreapta jos a ecranului va incepe sa numere de la "65" in jos si operatorul va avea 3 secunde inainte ca triplul bip sa avertizeze operatorul sa introduca stripul in proba de urina.
3. In timp ce auziti triplul bip si/sau vedeti cronometrul ajungand la "62", introduceti complet partea de reactiv a stripului in urina proaspata, bine amestecata si indepartati imediat stripul pentru a evita dizolvarea reactivilor.



4. In timp ce scoateti stripul din urina, treceti muchia stripului de marginea recipientului probei de urina pentru a indeparta urina in exces. Tineti stripul in pozitie orizontala si aduceti muchia stripului in contact cu un material absorbant (ex. prosop hartie) pentru a evita amestecarea substantelor chimice din zonele invecinate si/sau murdarirea mainilor cu urina.





5. Asezati stripul cu fata in sus in canalul suportului pentru stripuri si asigurati-va ca, capatul stripului atinge opritorul suportului pentru stripuri asa cum este aratat mai jos.



**Nota:**

- Cand cronometrul ajunge la "1", suportul pentru stripuri va duce stripul in interior si va incepe analiza.
  - Analizorul efectueaza o calibrare automata la fiecare test.
  - Rezultatele vor fi afisate pe ecran si inregistrate in memorie automat.
  - Rezultatele vor fi printate automat daca modul "Auto-Print" este activ. Daca modul "Auto-Print" este inactiv, operatorul trebuie sa apese tasta Print pentru a printa rezultatele.
6. Indepartati stripul folosit din suport o data ce acesta este scos afara. Inlaturati stripurile folosite conform regulilor locale.
  7. Repetati punctele 2-6 descrise mai sus pentru a testa si alte probe de urina.
  8. Efectuati spalarea zilnica cand analizele din ziua respectiva sunt incheiate. Trimitere la **Curatarea zilnica** de la pagina 19.

**Masurarea in modul de lucru continuu**

*Folositi modul de lucru continuu pentru a analiza un numar mare de stripuri unul dupa altul. Trimitere la **Selectarea modului de lucru single sau modului de lucru continuu** de la pagina 11 pentru instructiuni in selectarea modului de lucru continuu.*

1. Apasati tasta Start pentru a intinde suportul pentru stripuri. Fereastra "Place a strip on the holder" va fi afisata cum este aratat mai jos.
2. Apasati tasta Start si asteptati triplul bip pentru a incepe introducerea stripului.

Nota: O data ce tasta Start este apasata, cronometrul din dreapta jos a ecranului va incepe sa numere de la "65" in jos si operatorul va avea 3 secunde inainte ca triplul bip sa avertizeze operatorul sa introduca stripul in proba de urina.

3. In timp ce auziti triplul bip si/sau vedeti cronometrul ajungand la "62", introduceti complet partea de reactiv a stripului in urina proaspata, bine amestecata si indepartati imediat stripul pentru a evita dizolvarea reactivilor.
4. In timp ce scoateti stripul din urina, treceti muchia stripului de marginea recipientului probei de urina pentru a indeparta urina in exces. Tineti stripul in pozitie orizontala si aduceti muchia stripului in contact cu un material absorbant (ex. prosop hartie) pentru a evita amestecarea substantelor chimice din zonele invecinate si/sau murdarea mainilor cu urina.
5. Asezati stripul cu fata in sus in canalul suportului pentru stripuri si asigurati-va ca, capatul stripului atinge opritorul suportului pentru stripuri asa cum este aratat mai jos.
6. Dupa auzirea urmatorului triplu bip si/sau observarea cronometrului ajungand la "32", introduceti un nou strip in urina proaspata, bine amestecata si repetati punctele 3-4 descrise mai sus. Apoi asezati noul strip pe un prosop de hartie cu fata in sus si asteptati ca suportul de stripuri sa iasa afara.
7. Dupa auzirea urmatorului triplu bip si/sau observarea cronometrului ajungand la "2", introduceti un nou strip in urina proaspata, bine amestecata si repetati punctele 3-4 descrise mai sus. Apoi asezati noul strip pe un prosop de hartie cu fata in sus si asteptati ca suportul de stripuri sa iasa afara.

Nota:

- Cand cronometrul ajunge la "1", suportul de stripuri va duce stripul in interior si va incepe analiza in timp ce cronometrul va reveni la "30". Apoi rezultatele vor fi afisate pe ecran si inregistrate in memorie automat. Rezultatele vor fi printate automat daca modul "Auto-Print" este activ.
  - Daca modul "Auto-Print" este inactiv, operatorul trebuie sa apese tasta Print pentru a printa rezultatele.
8. Indepartati stripul folosit din suportul de stripuri dupa ce citirea este completa si suportul de stripuri este scos afara, apoi asezati imediat un nou strip in suportul de stripuri inainte ca, cronometrul sa ajunga la "1" si ca suportul de stripuri sa duca noul strip in interior si sa inceapa analiza.

Nota:

- Inainte ca, cronometrul sa ajunga la "1" si ca suportul de stripuri sa fie tras inapoi si sa inceapa analiza, operatorul va avea cam 8 secunde sa inlature stripul folosit si sa aseze un nou strip in suportul de stripuri.
  - Dupa ce cronometrul va ajunge prima data la "1", se va intoarce la "30" in loc de "65" pentru toate stripurile urmatoare. Un triplu bip va urma dupa fiecare 30 secunde, atentionand operatorul sa introduca un nou strip.
  - Inlaturati stripurile folosite conform regulilor locale.
9. Repetati punctele 7-8 descrise mai sus pentru a testa si alte probe de urina.
  10. Cand toate probele au fost testate, apasati tasta Cancel pentru a opri testarea.
  11. Efectuati spalarea zilnica cand analizele din ziua respectiva sunt incheiate. Trimitere la **Spalarea zilnica** de la pagina 19.

## Capitolul 5. Baza de date si Memoria

### Localizarea numerelor clinice si vizualizarea rezultatelor

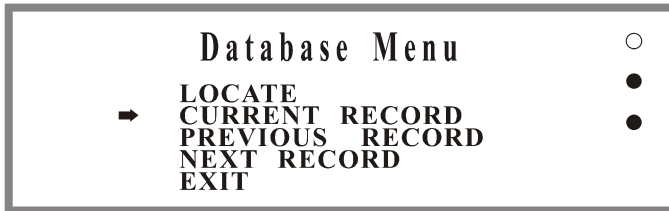
*Gasiti si revizuiti rezultate clinice stocate in analizor.*

#### Pasul 1. Navigare prin "Database Menu"

*Deschideti "Database Menu".*

Folositi tastele sageti pentru a selecta "Database" din meniul principal apoi apasati tasta Enter pentru a vizualiza baza de date, asa cum este aratat mai jos.

Nota: Trimitere la **Meniul principal** de la pagina 5 pentru a naviga in meniul principal.



#### Pasul 2. Localizarea numerelor clinice

*Cautati rezultate clinice in baza de date.*

1. Apasati sageata sus (↑) pentru a selecta "LOCATE" din meniul "Database Menu", aratat mai sus.
2. Apasati tasta Enter pentru a vizualiza fereastra, asa cum este aratat mai jos.



3. Folositi tastele cu numere pentru a introduce numarul clinic dorit apoi apasati tasta Enter pentru a vizualiza rezultatele.

Nota:

- Apasati tasta Clear pentru a sterge numarul introdus gresit apoi tastati numarul corect.
  - Daca nu a fost gasit nici un rezultat in baza de date dupa introducerea unui numar, va fi afisata o fereastra "Record not found!". Apasati orice tasta pentru a reveni in meniul "Database Menu".
4. Apasati tasta Print pentru a printa rezultatele afisate.
  5. Apasati sageata stanga (←) sau sageata sus (↑) pentru a vizualiza rezultatul anterior, sau apasati sageata dreapta (→) sau sageata jos (↓) pentru a vizualiza rezultatul urmator. Apoi apasati tasta Print pentru a printa rezultatul afisat pe ecran.
  6. Apasati tasta Cancel pentru a va intoarce la meniul "Database Menu" si repetati **Localizarea rezultatelor clinice** pentru a localiza diferite numere clinice cum s-a descris mai sus.

### Pasul 3. Vizualizarea rezultatelor curente, anterioare si urmatoare

*Vizualizati si navigati intr-o lista de rezultate clinice din baza de date.*

1. Folositi tastele sageti pentru a selecta "CURRENT RECORD", "PREVIOUS RECORD", sau "NEXT RECORD" apoi apasati tasta Enter pentru a revizualiza si printa rezultatele de care aveti nevoie.

Nota: Aceeasi operatie poate fi efectuata urmarind punctul 5 din **Localizarea rezultatelor clinice** de la pagina 16.

2. Apasati tasta Cancel pentru a va intoarce in meniul "Database Menu", apoi folositi tastele sageti pentru a selecta "EXIT" pentru a va intoarce.

#### Transferarea bazei de date

Pentru a transfera baza de date, conectati un cablu RS-232C de la un computer la un port standard RS-232C situat in spatele analizorului. Cablul si software-ul vor permite ca toate datele sa fie stocate intr-o baza de date externa din computer unde sunt posibile manipularea datelor si divizarea unei retele extinse.

#### Memoria

*Se pot stoca pana la 500 rezultate care pot fi revazute oricand.*

Toate rezultatele testelor vor fi automat inregistrate in memorie. Memoria poate stoca pana la 500 rezultate. Pentru a garanta siguranta datelor si a utiliza memoria la capacitate maxima, folositi intotdeauna un numar clinic care urmeaza numarului clinic anterior.

#### Atentie:

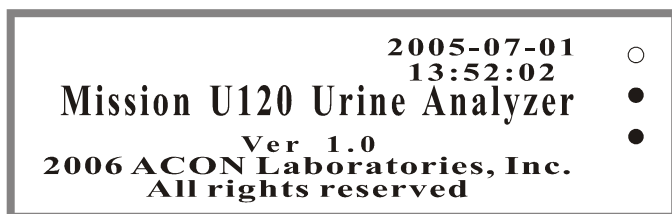
- Baza de date va inregistra peste rezultatele stocate anterior daca numarul de rezultate depaseste 500. Daca exista deja 500 rezultate in memorie, cel mai vechi rezultat va fi sters. De exemplu, al 501-lea rezultat il va inlocui pe primul rezultat din memorie.
- Daca numarul clinic este schimbat si un numar clinic este la fel cu un numar clinic inregistrat anterior in memorie, datele numarului clinic anterior vor fi sterse si rezultatul va fi inlocuit cu noile date.

#### Stergerea memoriei

*Se poate sterge intreaga memorie din baza de date.*

1. Navigati in ecranul principal, asa cum este aratat mai jos.

Nota: Trimitere la **Ecranul principal** de la pagina 5 pentru a naviga in ecranul principal.



2. Apasati tasta Clear si va fi afisata fereastra "CLEAR THE DATA", asa cum este aratat ami jos.



3. Apasati tasta Enter pentru a sterge memoria, sau apasati orice alta tasta pentru a iesi din fereastra fara a sterge memoria existenta.

**Atentie:** Daca este apasata tasta Enter, va fi auzit un bip cvadruplu, indicand ca baza de date a fost stearsa si nici un rezultat nu poate fi recuperat. Numarul clinic standard va reveni la 000001.

## Capitolul 6. Comunicarea datelor

Analizorul este echipat cu doua porturi de comunicare incluzand un port pentru imprimanta externa cu 25 pini si un port standard RS-232C.

Analizorul are nevoie de o imprimanta externa cu cablu pentru a printa extern. Trimitere la **Imprimanta externa sau interna** de la pagina 8 pentru a folosi o imprimanta externa.

Analizorul are nevoie de un cablu RS-232C conectat la un computer cu soft-ul instalat pentru a transfera baza de date. Cablul si soft-ul vor permite ca toate datele generate in timpul testarii sa fie stocate intr-o baza de date externa din computer unde sunt posibile manipularea datelor si divizarea unei retele extinse. Trimitere la **Transferarea bazei de date** de la pagina 17 pentru detalii.

## Capitolul 7. Controlul de calitate

Pentru rezultate optime ar trebui confirmata performanta stripului cu reactivi cu ajutorul unor specimene negative/pozitive cunoscute sau martori (controale) de fiecare data cand se introduce un nou test sau la deschiderea unui nou flacon. Fiecare laborator trebuie sa isi stabileasca propriile proceduri pentru standardele de performanta.

## Capitolul 8. Intretinerea

### Precautiuni

*Urmati precautiunile listate mai jos pentru a garanta rezultate precise si durabilitate analizorului.*

- Feriti analizorul de lumina directa a soarelui si de campuri magnetice in timpul testarii pentru a asigura acuratetea rezultatelor.
- Nu asezati niciodata nimic in fata suportului de stripuri pentru a evita coliziunea atunci cand suportul de stripuri este scos afara.
- Pastrati analizorul curat si stergeti-l des cu o carpa uscata, moale si curata. Folositi apa proaspata cand este cazul.
- Nu curatati analizorul cu substante ca benzina, dizolvant de vopsea, compusi benzenici sau alti solventi organici pentru a evita deteriorarea suportului de stripuri, cercului alb de calibrare, sau altor componente.
- Nu spalati ecranul cu cristale lichide cu apa. Pentru a-l curata, stergeti usor cu o carpa curata, moale si uscata sau cu un prosop de hartie.
- Suportul pentru stripuri trebuie pastrat curat. Stergeti zilnic folosind apa proaspata. Trimiteri la **Curatarea zilnica** de la pagina 19.
- La aruncarea analizorului si a accesoriilor uzate respectati precautiunile corespunzatoare si toate regulamentele locale.
- Nu folositi analizorul sau stripurile in afara intervalului de temperatura afisat mai jos pentru a garanta acuratete rezultatelor:
  - Analizorul: 0-40°C (32-104°F)
  - Stripurile: 15-30°C (59-77°F)

### Curatarea zilnica

*Folositi instructiunile de mai jos dupa incheierea zilei de lucru.*

#### Pasul 1. Indepartati suportul de stripuri

1. Apasati tasta Enter pentru a intinde suportul de stripuri.
2. Inchideti intrerupatorul dupa ce suportul a fost intins.
3. Trageti suportul usor inapoi de ambele capete asa cum este aratat mai jos.

#### Pasul 2. Curatati suportul de stripuri

1. Curatati zilnic suportul de stripuri folosind un tampon de vata cu apa distilata apoi uscati cu un tampon de vata uscat si curat.
2. Verificati zilnic cercul alb de calibrare pentru a va asigura ca nu exista taieturi sau murdarie. Curatati periodic cercul alb de calibrare folosind un tampon de vata cu apa distilata apoi uscati cu un tampon de vata uscat si curat.

**Nota:** Cercul alb de calibrare trebuie inlocuit daca sunt descoperite taieturi sau murdarie care nu se poate indeparta. Contactati distribuitorul local daca sunt descoperite taieturi sau murdarie care nu se poate indeparta in cercul alb de calibrare.

#### Pasul 3. Incarcati suportul de stripuri

1. Prindeti suportul de stripuri asa cum este aratat mai jos.
2. Introduceti suportul de stripuri in fixatorul suportului.  
**Nota:** Cand este corect pozitionat, suportul de stripuri va pocni si va fi fixat in loc, iar cercul alb de calibrare nu va fi vizibil. Vezi ilustratia de mai jos.



#### **Pasul 4. Readuceti suportul de stripuri in pozitia originala**

1. Deschideti intrerupatorul.
2. Asteptati ca suportul de stripuri sa inceapa sa se miste in interiorul analizorului.
3. Inchideti intrerupatorul cand suportul este in interiorul analizorului, sau incepeti testarea stripurilor referindu-va la **Instructiunile de operare** de la pagina 12.

#### **Curatarea alcalin urica**

*Urmati instructiunile de mai jos cand optiunea alcalin urica este prezenta.*

1. Indepartati suportul de stripuri urmand **Indepartati suportul de stripuri** de la pagina 19.
2. Curatati suportul de stripuri folosind un tampon de vata cu 0.1 N NaOH.  
**Atentie:** Nu permiteti ca solutia de NaOH sa atinga cercul alb de calibrare.
3. Curatati excesul de NaOH de pe suport folosind o carpa inmuata in apa distilata.
4. Uscati suportul cu un tampon de vata uscat si curat.
5. Incarcati suportul si aduceti-l in pozitia originala asa cum este descris la pagina 20.

#### **Procesul de sterilizare**

*Urmati instructiunile de mai jos pentru a steriliza suportul de stripuri atunci cand acesta intra in contact cu probe de urina.*

1. Indepartati suportul de stripuri si repetati **Curatarea zilnica** de la pagina 19.
2. Curatati suportul de stripuri folosind un tampon de vata cu una dintre urmatoarele solutii de sterilizare:
  - 2% glutaraldehida (densitate suficienta): Trimitere la instructiunile detaliate de pe eticheta produsului.
  - 0.05% sotiie hipoclorit de sodiu: Adaugati 1 mL 5% hipoclorit de sodiu in 99 mL apa distilata, sau preparati o dilutie 1: 100 cu un volum final diferit.
  - Alcool isopropilic (70-80%).
3. Turnati solutia sterilizatoare intr-un vas ingust de 10 cm (4 inci) inaltime.
4. Introduceti suportul de stripuri in solutia sterilizatoare si **asigurati-va sa pastrati cercul alb de calibrare afara din solutie.**
5. Inmuiati suportul de stripuri in solutia sterilizatoare pentru 10 minute.
6. Scoateti suportul, stergeti-l si uscati-l.
7. Incarcati suportul si readuceti-l in pozitia originala asa cum este descris la pagina 20.

## Capitolul 9. Auto-controlul manual si defectiuni

### Auto-controlul manual

*Un diagnostic intern este incorporat in analizor pentru a ajuta in procesul defectiunilor.*

1. Apasati sageata sus (↑) pentru a selecta "Self Test" din meniul principal.  
Nota: Trimitere la **Meniul principal** de la pagina 5 pentru a naviga in meniul principal.
2. Apasati tasta Enter pentru a incepe auto-controlul manual. Suportul de stripuri se va misca de doua ori in interior si in afara si rezultatele auto-controlului vor fi afisate asa cum este aratat mai jos.

Self Test Results	
MAIN CONTROL UNIT	P a s s e d
OPTICAL SENSOR	P a s s e d
TEST ACCURACY	P a s s e d
MECHANIC UNIT	P a s s e d
EXCEED LIGHT	P a s s e d








Nota:

- Daca analizorul functioneaza corect, "Passed" va fi afisat langa fiecare din testele aratate mai sus.
  - In cazul unei defectiuni, "Failed" va fi afisat langa testul respectiv si operatorul va trebui sa mearga la **Tabelul de defectiuni** de mai jos in gasirea solutiei.
3. Apasati orice tasta pentru a reveni la meniul principal.



## Tabel de defectiuni

Urmatorul tabel indica solutii pentru fiecare problema.

Problema	Solutii
	<ul style="list-style-type: none"> <li>• Potriviti stripul astfel incat capatul stripului sa atinga complet opritorul suportului de stripurisi sa fie centrat in canalul suportului</li> <li>• Verificati daca suportul de stripuri este pozitionat corect in fixatorul suportului</li> </ul>
	<ul style="list-style-type: none"> <li>• Introduceti stripul</li> </ul>
Nimic afisat pe ecran	<ul style="list-style-type: none"> <li>• Deschideti intrerupatorul</li> <li>• Verificati siguranta din spatele analizorului pentru a vedea daca este deteriorata si inlocuiti-o daca este necesar</li> </ul>
Siguranta este deteriorata	<ul style="list-style-type: none"> <li>• Inchideti intrerupatorul, scoateti din priza si inlocuiti siguranta deteriorata cu una noua de 2.0A</li> </ul>
Imprimanta nu functioneaza	<ul style="list-style-type: none"> <li>• Setati "Auto-Print" in pozitia "On". Trimite la <b>Setarea imprimantei</b> de la pagina 7</li> <li>• Incarcati cu hartie daca este necesar</li> <li>• Asigurati-va ca imprimanta este setata pe "Internal" daca nu este conectata o imprimanta externa. Trimite la <b>Setarea imprimantei</b> de la pagina 7</li> <li>• Clar cu ethanol (C<sub>2</sub>H<sub>6</sub>O)</li> </ul>
	<ul style="list-style-type: none"> <li>• Inchideti intrerupatorul apoi executati un auto-control. Trimite la <b>Auto-controlul manual</b> de la pagina 21</li> </ul>
	<ul style="list-style-type: none"> <li>• Asigurati-va ca suportul de stripuri este pozitionat corect in fixator. Trimite la <b>Curatarea zilnica</b>, pasul 3 de la pagina 19</li> <li>• Curatati suportul de stripuri. Trimite la <b>Curatarea zilnica</b>, pasul 2 de la pagina 19</li> <li>• Inchideti intrerupatorul apoi executati un auto-control. Trimite la <b>Auto-controlul manual</b> de la pagina 21</li> </ul>
	<ul style="list-style-type: none"> <li>• Inchideti intrerupatorul apoi reveniti si efectuati un auto-control. Trimite la <b>Auto-controlul manual</b> de la pagina 21</li> </ul>
	<ul style="list-style-type: none"> <li>• Indepartati orice obstacol din calea suportului de stripuri</li> <li>• Nu atingeti suportul de stripuri cand se misca</li> <li>• Inchideti intrerupatorul apoi reveniti si efectuati un auto-control. Trimite la <b>Auto-controlul manual</b> de la pagina 21</li> </ul>
	<ul style="list-style-type: none"> <li>• Inchideti intrerupatorul apoi reveniti si efectuati un auto-control. Trimite la <b>Auto-controlul manual</b> de la pagina 21</li> </ul>

Contactati distribuitorul local pentru a primi suport tehnic in caz ca nu puteti rezolva problemele.

## Anexa 1. Specificatiile analizorului de urina si stripuri compatibile

### Specificatii analizor urina U120

Caracteristici	Specificatii
Metodologie	Fotometru cu factor de reflexie
Detectie	Dioda fotosensibila
Capacitate de lucru	Modul de lucru single: 40 teste/ora Modul de lucru continuu: 120 teste/ora
Memorie	500 rezultate
Timp de incubare a stripului	1 minut
Lungimea de unda a LED-ului monocromatic	565 nm si 635 nm
Port PC	Port standard RS 232C (cablul nu este inclus)
Posibilitati de printare	Imprimanta interna termo-sensibila (inclusa) Imprimanta externa (nu este inclusa) Port cu 25 pini pentru imprimanta externa (inclus)
Limba disponibila	Engleza si spaniol
Conditii ambiente de lucru	0-40°C (32-104°F); ≤85% umiditate
Conditii optime de lucru	15-30°C (59-86°F); ≤75% umiditate
Sursa de curent	110-230 volti AC, 50-60Hz
Contactator cu disjunctur*	0,5 mA
Greutate	2,6 Kg (5,73 lbs)
Dimensiuni (L X I X I)	27,1 cm × 26,5 cm × 14,8 cm (10,6" X 10,3" X 5,8")
Dimensiunile ecranului (I X I)	10,6 cm × 2,8 cm (4,1" X 1,1")

Acest produs respecta normele EN 61326.

\*Protocolul de lucru si limitele permise asa cum sunt specificate de catre standardele de securitate pentru echipamente de laborator evidentiare in UL 1262 si CSA 22.2 Nr. 151.

### Stripuri compatibile

# de parametri	Codul stripului	Analize
8	A08	Nitriti, Urobilinogen, Proteine, Ph, Hematii, Corpi cetonic, Bilirubina si Glucoza
9	A09	Nitriti, Urobilinogen, Proteine, Ph, Hematii, Densitate, Corpi cetonic, Bilirubina si Glucoza
10	A10	Leucocite, Nitriti, Urobilinogen, Proteine, Ph, Hematii, Densitate, Corpi cetonic, Bilirubina si Glucoza
11	A11	Leucocite, Nitriti, Urobilinogen, Proteine, Ph, Hematii, Densitate, Corpi cetonic, Bilirubina, Glucoza si Acid ascorbic

Nota:

- Asigurati-va ca tipul de strip selectat corespunde cu stripul care va fi folosit. Folosirea oricarui alt strip poate cauza rezultate incorecte.
- Folositi numai stripuri din aceeasi gama cu analizorul pentru a asigura o functionare corecta si rezultate precise.

## Anexa 2. Specificatiile stripurilor si printarea rezultatelor

In concordanta cu tipul de stripuri folosite, analizorul recunoaste automat in ce ordine sunt localizati parametrii si la fel ii afiseaza si ii prindeaza. Rezultatele arbitrare vor fi intotdeauna printate automat in timp ce rezultatele SI sau conventionale vor fi printate in concordanta cu setarea unitatilor selectata. Trimitere la **Setarea unitatilor** de la pagina 9.

**Tabel parametri stripuri de urina**

Numele parametrului (Abrevierea pe ecran)	Arbitrar	Conventional	SI
Leukocite (LEU)	- ± 1+ 2+ 3+	Leu/µL 15 Leu/µL 70 Leu/µL 125 Leu/µL 500 Leu/µL	Leu/µL 15 Leu/µL 70 Leu/µL 125 Leu/µL 500 Leu/µL
Nitriti (NIT)	- +	N/A	N/A
Urobilinogen (URO)	- ± 1+ 2+ 3+	0.2 mg/dL 1 mg/dL 2 mg/dL 4 mg/dL 8 mg/dL	3.5 µmol/L 17 µmol/L 35 µmol/L 70 µmol/L 140 µmol/L
Proteine (PRO)	- ± 1+ 2+ 3+	mg/dL 15 mg/dL 30 mg/dL 100 mg/dL 300 mg/dL	g/L 0.15 g/L 0.3 g/L 1.0 g/L 3.0 g/L
pH	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0
Hematii (BLO)	- ± 1+ 2+ 3+	Ery/µL 10 Ery/µL 25 Ery/µL 80 Ery/µL 200 Ery/µL	Ery/µL 10 Ery/µL 25 Ery/µL 80 Ery/µL 200 Ery/µL
Densitate (SG)	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030
Corpi cetonic (KET)	- ± 1+ 2+ 3+	mg/dL 5 mg/dL 15 mg/dL 40 mg/dL 80 mg/dL	mmol/L 0.5 mmol/L 1.5 mmol/L 4.0 mmol/L 8.0 mmol/L
Bilirubina (BIL)	- 1+ 2+ 3+	mg/dL 1 mg/dL 2 mg/dL 4 mg/dL	µmol/L 17 µmol/L 35 µmol/L 70 µmol/L
Glucoza (GLU)	- ± 1+ 2+ 3+	mg/dL 100 mg/dL 250 mg/dL 500 mg/dL 1000 mg/dL	mmol/L 5 mmol/L 15 mmol/L 30 mmol/L 60 mmol/L
Acid ascorbic (ASC)	- 1+ 2+ 3+	mg/dL 10 mg/dL 20 mg/dL 40 mg/dL	mmol/L 0.6 mmol/L 1.2 mmol/L 2.4 mmol/L

Nota:

- Arbitrar:
  - Toate rezultatele pozitive cu exceptia pH-ului, densitatii (SG) vor fi raportate ca 1+, 2+, sau 3+.
  - Rezultatele pozitive pentru pH si densitate (SG) vor fi raportate cu datele respective.
  - Rezultatele negative pentru leucocite, nitriti, urobilinogen, proteine, hematii, glucoza si acidului ascorbic vor fi raportate cu "-".
- Conventional sau SI:
  - Toate rezultatele pozitive cu exceptia nitritilor (NIT) vor fi raportate cu datele respective in fata unitatilor.
  - Toate rezultatele negative cu exceptia nitritilor (NIT) vor fi raportate cu un spatiu liber in fata unitatilor.
  - Rezultatele pentru nitriti (NIT) nu vor fi raportate in unitati SI sau conventionale ci vor fi raportate in unitati arbitrare.

### Printarea rezultatelor

Data, ora si numarul clinic vor fi printate impreuna cu rezultatele in unitati arbitrare. Rezultatele atat in unitati SI sau conventionale vor fi printate in functie de selectarea unitatii.

DATE:	2006-07-01	15:44
No.	000037	
LEU	-	Leu/ $\mu$ L
NIT	-	
URO	-	0.2 mg/dL
PRO	-	mg/dL
pH		5.5
BLO	-	Ery/ $\mu$ L
SG		1.030
KET	$\pm$	5 mg/dL
BIL	-	mg/dL
GLU	1+	250 mg/dL
ASC	2+	20 mg/dL

### Anexa 3. Catalog

Numele produsului	Numar de catalog	Componente	Cantitate
Analizor urini U120	U111-101	Analizor urini U120	1
		Suport de stripuri	1
		Role hartie imprimanta	2
		Sigurante (2.0A)	2
		Cablu curent	1
		Manual instructiuni	1
Role hartie imprimanta	U121-101	Role hartie imprimanta	4

#### Anexa 4. Simboluri

	Atentie, vezi instrucțiunile de folosire		Producator		Reprezentant autorizat
	Numai pentru uz <i>in vitro</i>		Numar lot	<b>REF</b>	Catalog #
	Ase pastra intre 0-40°C		Teste pe kit	<b>SN</b>	Numar serie
	Feriti de soare si lumina		Folositi pana la	<b>IOIOI</b>	Port serial
	Pastrati uscat		Fragil, manevrati cu grija		Aceasta parte in sus

## **Anexa 5. Garantie**

Completati cardul de garantie inclus in impachetare si trimiteti-l distribuitorului local pentru a va inregistra achizitionarea produsului in mai putin de 30 zile de la achizitionare.

Pentru inregistrarile d-voastra, notati data achizitionarii kitului de start aici:

---

Nota: Aceasta garantie se aplica numai analizorului din pachetul original si nu se aplica altor materiale de pe langa analizor.

**ACON Laboratories, Inc.** garanteaza achizitorului ca acest analizor nu va avea defecte in materia prima si mana de lucru pentru o perioada de 90 zile (3 luni) de la data achizitionarii sau instalarii (cu exceptia celor notate mai jos). In perioada de 90 zile, ACON va inlocui marfa aflata in garantie cu una reconditionata, sau ca optiune, va repara fara cost marfa gasita defecta. ACON nu va fi responsabil pentru costurile de transport ale analizorului ce va fi reparat.

Garantia face subiectul urmatoarelor exceptii si limitari:

Garantia este limitata la repararea sau inlocuirea in cazul defectelor in componente sau mana de lucru. Componentele cerute care nu au fost defecte vor fi inlocuite la costuri additionale, si ACON nu va face nici o reparatie sau inlocuire a componentelor abuzate, accidentate, transformate, folosite gresit, neglijate, in caz de operare eronata a analizorului sau intretinere efectuata de altcineva in afara de ACON. Mai mult de atat, ACON nu isi asuma raspunderea pentru functionarea defectuoasa sau degradarea analizoarelor cauzate de folosirea altor stripuri decat cele fabricate de ACON. ACON isi rezerva dreptul sa faca schimbari in designul acestui analizor fara obligatia de a introduce aceste schimbari in analizoarele fabricate anterior.

### **Negarea altor garantii**

Aceasta garantie tine locul oricaror alte garantii exprimate sau presupuse (fie in fapt sau prin lege) incluzand garantiile de comercializare si aptitudinile de folosire, care sunt excluse in mod expres, si este singura garantie oferita de ACON.

### **Limitarea obligatiilor**

In nici un caz ACON nu va fi obligat pentru deteriorari consecvente, speciale, sau indirecte, chiar daca ACON a fost informat de aceste deteriorari.

Pentru garantia de service, contactati distribuitorul local ACON.

### **Mission™ Card garantie analizor urini U120**

Completati aceasta garantie si trimiteti-o distribuitorului local pentru a va inregistra marfa in mai putin de 30 zile de la achizitionare. Trimitere la **Anexa 5. Garantie** din manualul de operare, pentru detalii si termeni de garantie.

Data achizitiei	Achizitor	Numar de serie al analizorului (ex. SN 0000000. Vezi eticheta din spatele analizorului)
Numele companiei		Adresa
Numar telefon		Adresa e-mail



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

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

#### INTENDED USE

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

#### PRECAUTIONS

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

#### REAGENTS

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

#### STORAGE AND STABILITY

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

#### MATERIALS

##### Materials Provided

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

##### Materials Required But Not Provided

- Strips
- Timer

#### DIRECTIONS FOR USE

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

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

Note:

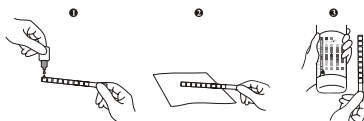
- Do not touch the tip of the urine control bottle to the reagent areas on the urinalysis reagent strip to avoid contamination.
- Dispense the remaining hanging drop of urine control before turning the urine control bottle upright.

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

Note:

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

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



#### EXPECTED VALUES

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

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

#### LIMITATIONS

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

#### Index of Symbols

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



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



MDSS GmbH  
Schiffgraben 41  
30175 Hannover, Germany



# Mission® Urinalysis Reagent Strips (Urine)

## Package Insert

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

For rapid detection of multiple analytes in human urine.

For *in vitro* diagnostic use only.

### INTENDED USE

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

### SUMMARY

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

### 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.<sup>3</sup> 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.<sup>4-6</sup> In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.<sup>7</sup>

**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.<sup>8</sup> Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022.<sup>9</sup> 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 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.<sup>9</sup> The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.<sup>9</sup>

**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.<sup>10</sup> 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).<sup>8</sup> 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.<sup>9</sup> The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

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

### REAGENTS AND PERFORMANCE CHARACTERISTICS

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

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

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

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

### PRECAUTIONS

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

### STORAGE AND STABILITY

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

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

### SPECIMEN COLLECTION AND PREPARATION

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

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

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

### MATERIALS

#### Materials Provided

- Strips
- Package insert

#### Materials Required But Not Provided

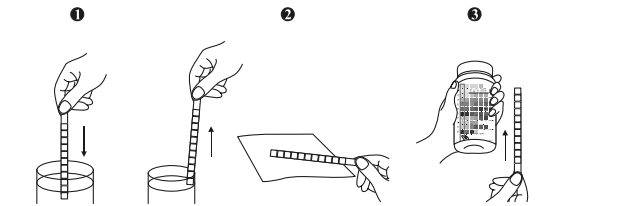
- Specimen collection container
- Timer

### DIRECTIONS FOR USE

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

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

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



### INTERPRETATION OF RESULTS

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

### QUALITY CONTROL

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

### LIMITATIONS

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

**Ascorbic acid:** No interference is known.

**Glucose:** The reagent area does not react with lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Sensitivity may be decreased in specimens with high specific gravity (>1.025) and with ascorbic acid concentrations of ≥ 25 mg/dL. High ketone levels ≥ 100 mg/dL may cause false negative results for specimens containing a small amount of glucose (50-100 mg/dL).

**Bilirubin:** Bilirubin is absent in normal urine, so any positive result, including a trace positive, indicates an underlying pathological condition and requires further investigation. Reactions may occur with urine containing large doses of chlorpromazine or rifampin that might be mistaken for positive bilirubin.<sup>9</sup> 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.<sup>8</sup> Urine specimens of high pigment, and other substances containing sulfindryl groups may occasionally give reactions up to and including trace (±).

**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.<sup>8</sup> 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.<sup>8</sup> 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.<sup>8</sup> 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.<sup>9</sup> False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.

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

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

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Index of Symbols			
	Consult instructions for use		Tests per kit
	For <i>in vitro</i> diagnostic use only		Use by
	Store between 2-30°C		Lot Number
	Authorized Representative		

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

**MDSS GmbH**  
Schiffgraben 41  
30175 Hannover, Germany



Date: 05/Jan/2023

### **STATEMENT**

We, Atlas Medical having a registered office at Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL Sanmedico having a registered office at A. Corobceanu Street 7A, apt.9, Chisinau MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Atlas Medical GmbH**  
Ludwig - Erhard Ring 3  
15827 Blankenfelde - Mahlow  
Tel. (0049) 33708 - 355030

**Atlas Medical:** Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany,  
Tel: +4933708355030

**Regulatory Office:** William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom  
Tel: +44 (0) 1223 858 910

**Middle East Site:** P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan  
Tel: +962 6 4026468

**GMED certifie que le système de management de la qualité développé par**  
*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**

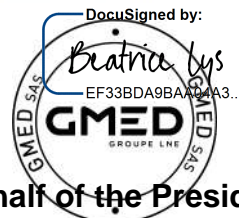


Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

GMED N° 36655-2

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

**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*  
FF33BDA98AA04A3...  
**GMED**  
GROUPE LNE

**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](mailto: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](mailto:info@atlas-medical.com)

Declare our responsibility that the following product:

**See Attached list**

- Comply with all essential requirements (Annex I) 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°:** 36655 rev 1  
**Expiry Date:** October 8<sup>th</sup>.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	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March.2021	09.03.2021		

## 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).



## CE Declaration of Conformity

<b>Name and address of Manufacturer</b>	<b>Atlas Medical GmbH</b> Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com
-----------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.04.21.0.0001	Atlas H. pylori Antibody Rapid Test Device (Serum/Plasma), Individually Pouched, Bulk	62029
8.04.21.0.0020	Atlas H. pylori Antibody Rapid Test Device (Serum/Plasma), Individually Pouched, 20 Tests/Box	62029
8.04.21.0.0030	Atlas H. pylori Antibody Rapid Test Device (Serum/Plasma), Individually Pouched, 30 Tests/Box	62029
8.04.20.0.0001	Atlas H. pylori Antibody Rapid Test Device (Whole blood/Serum/Plasma), Individually Pouched, Bulk	62029
8.04.20.0.0020	Atlas H. pylori Antibody Rapid Test Device (Whole blood/Serum/Plasma), Individually Pouched, 20 Tests/Box	62029
8.04.20.0.0030	Atlas H. pylori Antibody Rapid Test Device (Whole blood/Serum/Plasma), Individually Pouched, 30 Tests/Box	62029

Meets the essential requirements of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I  
And

EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016  
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,  
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

<b>IVD Categorization</b>	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
<b>Conformity Assesment Route</b>	Directive 98/79/EC , Annex III.
<b>Name , Address and Identification number of notified body</b>	N/A

<b>Date of issuance:</b>	06.September.2021
<b>Place</b>	Atlas Medical GmbH
<b>Signed by:</b>	Amani AL-Hababbeh
<b>Position :</b>	Regulatory Affairs Manager

**Atlas Medical GmbH**  
Ludwig - Erhard Ring 3  
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Tel. (0049) 33708 - 355030

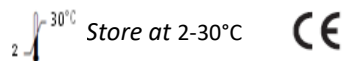
MRXDO10F.11  
11.08.2021





## Atlas *H. pylori* Antibody Rapid Test Device (Whole blood/Serum/Plasma)

**IVD** For *in vitro* diagnostic and professional use only



### INTENDED USE

The Atlas *H. pylori* Antibody Rapid Test Device (Whole blood/Serum/Plasma) is a rapid immune-chromatographic assay for the qualitative detection of antibodies to *Helicobacter pylori* in human Whole blood, serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of *H. pylori* infection.

### INTRODUCTION

*H. pylori* is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. Individuals infected with *H. pylori* develop antibodies which correlate strongly with histologically confirmed *H. pylori* infection.

Atlas *H. Pylori* Antibody Rapid Test is an immune-chromatographic assay that uses double antigen sandwich technology to detect the presence of *H. pylori* antibody in human blood specimens. The test is simple and easy to perform and the test results can be visually interpreted within 10 minutes.

### PRINCIPLE

Atlas *H. Pylori* Antibody Rapid Test employs chromatographic lateral flow test device in a cassette format. Colloidal gold conjugated *H. pylori* antigens (Au-Ag) are dry-immobilized at the end of nitrocellulose membrane strip. *H. Pylori* antigens are bonded at the Test Zone (T) when the sample is added; it migrates by capillary diffusion rehydrating the gold conjugate. If anti-*H. pylori* antibodies present in sample, Antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by *H. pylori* antigens generating a visible red line. If there are no anti-*H. Pylori* antibodies in sample, no red line is formed in the Test Zone (T). A built-in control line will always appear in the Control Zone (C) when the test has performed properly, regardless of the presence or absence of anti-*H. pylori* antibodies in the specimen.

### MATERIALS

#### MATERIALS PROVIDED

- *H. Pylori* Antibody Test Devices.
- Disposable Droppers.
- Buffer (For Whole blood sample only)
- Package insert.

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers.
- Timer.
- Centrifuge.

#### PACKAGING CONTENT

- REF 8.04.20.0.0001 (1 Individually Pouched Test Cassette, Buffer)**
- REF 8.04.20.0.0010 (10 Individually Pouched Test Cassette, Buffer)**
- REF 8.04.20.0.0020 (20 Individually Pouched Test Cassette, Buffer)**
- REF 8.04.20.0.0025 (25 Individually Pouched Test Cassette, Buffer)**
- REF 8.04.20.0.0030 (30 Individually Pouched Test Cassette, Buffer)**

### PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Do not use the test if the label was not available or damaged.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- **The test should be performed in a well lit area.**
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- All specimen should be considered potentially hazardous and in the same manner as infectious agent.
- Used testing materials should be discarded according to local regulations.

### STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.

- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

### SPECIMEN COLLECTION AND STORAGE

- The *H. pylori* Antibody Rapid Test Device (Whole blood/Serum/Plasma) is intended for use with human Whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept at -20°C for 3 months.
- The test works best on fresh whole blood samples. If testing cannot be done immediately, Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Sodium and Potassium Oxalate should be stored at 2-8°C up to 3 days. Blood samples should not be frozen.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

### PROCEDURE

**Bring tests and specimens to room temperature (15-30°C) before use.**

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Once opened, Use the test device immediately.

#### FOR SERUM AND PLASMA SAMPLES

2. Using a disposable dropper, transfer **2-3 drop of specimen (approximately 80 -120 µL)** to the sample pad of the Device.
3. At the end of 10 minutes read the results. A strong positive sample may show result earlier.

#### FOR WHOLE BLOOD SAMPLES

4. Using a disposable dropper, transfer **1 drop of specimen (approximately 40 µL)** to the sample pad of the Device .then add **one drop of buffer (approximately 40 µL)**.
5. At the end of **10 minutes** read the results. A strong positive sample may show result earlier.



## INTERPRETATION OF RESULTS PLEASE REFER TO THE ILLUSTRATION BELOW

### POSITIVE RESULTS

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

### NEGATIVE RESULTS

Only one colored band appears, in the control region (C). No colored band appears in the test region (T).

### INVALID RESULTS

If after 10 minutes no line is visible within the Control Zone, the result is invalid. The test should be repeated with a new test card.



## QUALITY CONTROL

- The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
- Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

## LIMITATIONS OF THE TEST

- The *H. pylori* Antibody Rapid Test Device (Whole blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of *H. pylori* antibodies. No meaning should be inferred from the color intensity or width of any apparent bands.
- This test should be used for symptomatic individuals with gastrointestinal disorders. Diagnosis of gastritis and/or peptic ulcers should be based on test results in conjunction with other clinical and laboratory findings.
- A positive result suggests only the presence of antibodies specific to *H. pylori*, and does not distinguish between active and past infections. A positive result is not necessarily indicative of gastrointestinal disease.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the possibility *H. pylori* infection, as antibodies to *H. pylori* may

be present below the minimum detection level of the test.

- Specimens from patients infected with *C. jejuni* may exhibit a low level of cross-reactivity in this test.

## PERFORMANCE CHARACTERISTICS

### 1. Accuracy

A panel of 1050 clinical samples were tested with reference commercially available *H. pylori* Antibody rapid test. The results are summarized in the following table:

Commercially <i>H. pylori</i> antibody test				
Rapid		Positive	Negative	Total
<i>H. pylori</i> AB Test	Positive	338	7	345
	Negative	9	696	705
	Total	347	703	1050

Sensitivity: 97.41% (95 CI: 95.13% to 98.81%).

Specificity: 99.0% (95 CI: 97.69% to 99.6%).

Overall agreement: 98.5% (95 CI: 97.4% to 99.0%).

### 2. Interference

No interference was found with bilirubin (10mg/dL), hemoglobin (20 mg/dL) or triglycerides (600 mg/dL) on the sensitivity and specificity of the test.

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PPI1513A01

Rev F (20.03.2023)

	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Do not re-use		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

# 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 (DVT) 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 8.00.17.0.0100** (D-Dimer Latex 1x2mL, 2x1.5mL 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 -20°C 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

- Bring reagents and specimens to room temperature before use.
- Place 20 µL of the reagent within a field on the reaction slide.
- Accurately pipette 20 µL of undiluted plasma or of control solution next to the drop of Latex Reagent.
- Mix the Latex Reagent and sample with a stirrer until the latex is uniformly distributed.
- Place the slide on a mechanical rotator at 80-100 r.p.m. for three minutes.
- 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

- 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
- 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  $\geq 0.80$  mg/L ( $\geq 800$  ng/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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PPI1473A01  
Rev D (06.05.2023)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <math>\leq 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

Document No.: GP-GMSQ-2023121301

## Letter of Authorization

To whom it may concern,

We, **Getein Biotech, Inc.** (No.9 Bofu Road, Luhe District, Nanjing, 211505, China), hereby authorize Sanmedico SRL (Address: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10 ) as our official and non-exclusive distributor for registration, promoting, selling, distributing and providing after-sale services of under-mentioned product in the territory of Moldova only:

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

Sanmedico SRL will comply with the laws and regulations of the countries and regions where they are located in and where they are selling mentioned product.

Sanmedico SRL will carry out marketing efforts to fulfill service and maintenance for above mentioned products and will provide with users benefits of having a local stock of above mentioned products and on-time delivery with every order, supported by a local service in local language.

This authorization starts from **1<sup>st</sup> Jan, 2024** and will be valid to **31th, December, 2024** .

Getein Biotech, Inc. has the right to terminate the authorization before validity and will inform Sanmedico SRL with 10 days in advance.

基蛋生物科技股份有限公司  
**Getein Biotech, Inc.**  
**GETEIN BIOTECH, INC.**  
Seal & Signature

Authority Person Name: **Steven Zhou**  
Authority Person Position: **Regional Manager**  
Date: **2023.12.13**



# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Getein Biotech, Inc.  
No.9 Bofu Road  
Luhe District  
Nanjing  
Jiangsu  
211505  
China

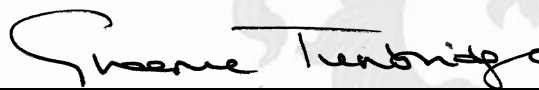
基蛋生物科技股份有限公司  
中国  
江苏省  
南京市  
六合区  
沿江工业开发区  
博富路9号  
邮编: 211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:



**Graeme Tunbridge, Senior Vice President Medical Devices**

Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 1 of 3



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Certificate No: **MD 728432**

## Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.

研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。



Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 2 of 3

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BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.



Certificate No: **MD 728432**

Location	Registered Activities
<p>Getein Biotech, Inc. No.9 Bofu Road Luhe District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京市 六合区 沿江工业开发区 博富路9号 邮编: 211505</p>	<p>Design &amp; Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design &amp; Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.</p> <p>研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。</p>
<p>Getein Biotech, Inc. No. 6 KeFeng Road Jiangbei New District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京 江北新区 科丰路6号 邮编: 211505</p>	<p>Manufacture of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), Colloidal Gold self-testing Assay to detect infectious disease. Manufacture of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.</p> <p>生产化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂和传染病相关胶体金自测试剂。 生产用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。</p>

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Page: 3 of 3

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BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands


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# Declaration of Conformity



according to Directive 98/79/EC, on in vitro diagnostic medical devices

<b>Maker</b> (Name, Address)	<b>Getein Biotech, Inc.</b> No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
<b>Authorized Representative</b> (Name, Address)	<b>Lotus Global Co., Ltd</b> 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom <i>2nd/Jan/2017 London</i>		
<b>Medical device</b>	<b>Description</b>	<p>Getein 100 Immunofluorescence Quantitative Analyzer</p> <p>Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)</p> <p>NT-proBNP Fast Test Kit (Immunofluorescence Assay)</p> <p>hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)</p> <p>NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)</p> <p>CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)</p> <p>D-Dimer Fast Test Kit (Immunofluorescence Assay)</p> <p>PCT Fast Test Kit (Immunofluorescence Assay)</p> <p><math>\beta_2</math>-MG Fast Test Kit (Immunofluorescence Assay)</p> <p>mAlb Fast Test Kit (Immunofluorescence Assay)</p> <p>NGAL Fast Test Kit (Immunofluorescence Assay)</p> <p>CysC Fast Test Kit (Immunofluorescence Assay)</p> <p>CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)</p> <p>HCG+<math>\beta</math> Fast Test Kit (Immunofluorescence Assay)</p> <p>HbA1c Fast Test Kit (Immunofluorescence Assay)</p> <p>TSH Fast Test Kit (Immunofluorescence Assay)</p> <p>TSH/T3/T4 Fast Test Kit (Immunofluorescence Assay)</p> <p>PCT/CRP Fast Test Kit (Immunofluorescence Assay)</p> <p>CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)</p> <p>H-FABP Fast Test Kit (Immunofluorescence Assay)</p>	
		Classification of products according to directive	: Others
		Batch/serial No. Type, production term (if applicable)	:
Applicable coordination standards:	EN ISO 14971:2012	EN ISO 23640:2015	EN ISO 13485:2016
	EN 980:2008	EN 13612:2002	EN ISO15223-1:2012
	EN 1041:2008	EN ISO 18113-1:2011	EN ISO 18113-2:2011
	EN ISO 18113-3:2011	EN-IEC 61326-1:2013	EN-IEC 61010-1:2010
	IEC 61010-2-101:2015	EN-IEC 61326-2-2:2013	
<p>Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.</p>			
General Manager: Enben Su			
<i>Nanjing, 3rd, Jan, 2017</i> (place and date of issue)		 (name and signature or equivalent marking of authorized person)	



Cardiac  
Markers

Coagulation  
Markers

Diabetes  
Mellitus

Inflammation

Thyroid  
Function

Metabolic  
Marker

Renal  
Function

Tumor  
Markers

Reproduction  
/Fertility

Infectious  
Disease



**Getein**  
Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

**MAKING TEST EASY**

# Getein 1100

Immunofluorescence Quantitative Analyzer



# Getein 1100

Immunofluorescence Quantitative Analyzer



## HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



## REAL-TIME AND RAPID TEST

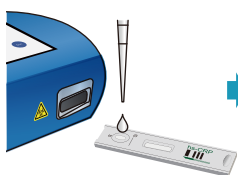
One-step test

3-15 min/test

5 sec/test for multiple tests

## OPERATION MODES

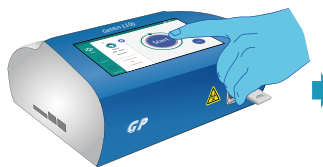
### Inside Mode (single sample rapid test mode)



Sample Transfer



Test Card Insert



Click "Start" Icon

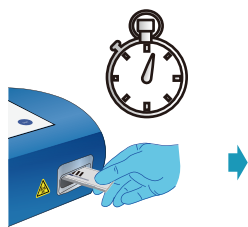


Result Show and Print

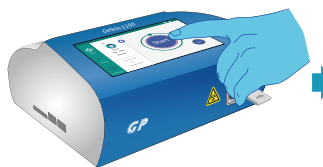
### Quick mode (mass samples rapid test mode)



Sample Transfer



Timing the Reaction Manually



Click "Start" Icon



Result Show and Print



## CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

Handwriting input available

Continuous test for 3 hours with optional lithium battery



## USER-FRIENDLY INTERFACE

Android system

7-inch touch screen



① 7-inch Touch Screen

② SD Card Recognition Zone

③ Test Card Slot

④ SD Card Slot

⑤ USB Slot

⑥ Built-in Thermal Printer



## PORTABLE DESIGN

Small in size: 261 × 241 × 115 mm

Light in weight: 2.0 kg



## LARGE MEMORY

Up to 10,000 results storage capacity

## TECHNICAL PARAMETERS

### Methodology

Immunofluorescence

### Result

Quantitative

### Sample Type

WB, Plasma, Serum, Urine, Stool,  
Nasal swab, Saliva, Capillary blood

### Storage Capacity

10000 data

### Language

English/Chinese/Spanish/Portuguese

### Screen

7-inch touch screen

### Power Supply

100-240 V~50 Hz/60 Hz, 60 VA

### Working Environment

Temperature: 10-35°C  
Relative humidity ≤ 70%  
Air pressure 70.0~106.0 kpa

### Dimensions

261 mm×241 mm×115 mm (D×W×H)

### Weight

2.0 kg

# TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION	
Cardiac Markers									
IF1001	cTnI	Myocardial infarction	0.10 ng/mL	S/P/WB	0.10-50.00 ng/mL	100 µL	10 min	NMPA	CE
IF1098	TnT	Myocardial infarction	14.0 pg/mL	S/P/WB	10.0-10000.0 pg/mL	100 µL	15 min	NMPA	CE
IF1089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA	CE
IF1002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA	CE
IF1005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL Myo: 70.0 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA	CE
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL	100 µL	10 min	CE	
IF1014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	100 µL	3 min	NMPA	CE
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 0.10 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.50-80.00 ng/mL 0.10-50.00 ng/mL 2.00-100.00 ng/mL	100 µL	10 min	NMPA	CE
IF1018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	CE	
Coagulation Marker									
IF1006	D-Dimer	Venous thromboembolism	0.50 mg/L	P/WB	0.10-10.00 mg/L	100 µL	10 min	NMPA	CE
Inflammation									
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3.0 mg/L 10.0 mg/L	S/P/WB/ Fingertip blood	0.5-200.0 mg/L	10 µL	3 min	NMPA	CE
IF1007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 min	NMPA	CE
IF1015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.10 ng/mL CRP: 3.0 mg/L	S/P/WB	0.10-50.00 ng/mL 0.5-200.0 mg/L	100 µL	15 min	NMPA	CE
IF1044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA	CE
IF1090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA	CE
IF1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	100 µL	15 min	NMPA	CE
Renal Function									
IF1008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.50-10.00 mg/L	10 µL	3 min	NMPA	CE
IF1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA	CE
IF1010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	10 µL	10 min	NMPA	CE
IF1011	β <sub>2</sub> -MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA	CE
Diabetes Mellitus									
IF1017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NGSP IFCC	NMPA CE
Metabolic Marker									
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P	8.00-70.00 ng/mL	40 µL	15 min	NMPA	CE
Thyroid Function									
IF1024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA	CE
IF1022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	40 µL	15 min	NMPA	CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA	CE
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	CE	
IF1068	fT4	Hyperthyroidism, hypothyroidism	12.00-22.00 pmol/L	S/P/WB	0.30-100.00 pmol/L	100 µL	15 min	CE	

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Reproduction/Fertility								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5.0-100000.0 mIU/mL	100 μL	10 min	NMPA CE
IF1055	LH	PCOS, infertility evaluation	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	200 μL	15 min	CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 μL	15 min	NMPA CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
NEW IF1073	Testosterone	Female polycystic ovary syndrome, male testosterone insufficiency	Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL	S/P	0.10-16.00 ng/mL	100 μL	15 min	CE
NEW IF1074	E2	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/mL	100 μL	15 min	CE
Tumor Markers								
IF1053	tPSA	Prostate cancer	4.00 ng/mL	S/P	0.50-100.00 ng/mL	100 μL	15 min	NMPA
IF1072	fPSA	Prostate cancer	1.00 ng/mL	S/P	0.05-30.00 ng/mL	100 μL	10 min	NMPA
IF1050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF1058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	100 μL	15 min	CE
IF1059	Anti-HIV	AIDS	1.00 S/CO	S/P	1.00-1000.00 S/CO	100 μL	15 min	
IF1064	HBsAg	Hepatitis B	1.00 IU/mL	S/P	1.00-100.00 IU/mL	100 μL	15 min	
NEW IF1063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 μL	15 min	
IF1084	2019-nCoV IgM/IgG	COVID-19	1.00 COI	S/P/WB		100 μL	10 min	CE
NEW IF1091	SARS-CoV-2 Antigen	COVID-19	1.00 COI	Nasal swab/Saliva		100 μL	15 min	CE
NEW IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB/ Fingertip blood		40 μL	15 min	CE
IF1047	<i>H. pylori</i>	<i>H. pylori</i> infection	5.0 ng/mL	Stool	1.0-200.0 ng/mL 3 drops (about 100 μL)		10 min	CE
NEW IF1086	Influenza A/B	Respiratory viral infection	1.00 S/CO	Nasal swab		100 μL	15 min	CE
NEW IF1136	Dengue NS1 Ag	Dengue virus infection	1.00 S/CO	S/P/WB	0.50-50.00 S/CO	100 μL	15 min	CE
Specific Protein and Rheumatism								
NEW IF1075	RF	Rheumatoid arthritis	15.9 IU/mL	S/P/WB	10.0-640.0 IU/mL	10 μL	10 min	CE
NEW IF1076	ASO	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	408.0 IU/mL	S/P/WB	60.0-1370.0 IU/mL	10 μL	10 min	CE
NEW IF1029	Anti-CCP	Rheumatoid arthritis	25.0 U/mL	S/P/WB	10.0-400.0 U/mL	10 μL	15 min	CE
Others								
NEW IF1077	Ferritin	Anemia/tumors	Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL	S/P	0.50-1000.00 ng/mL	10 μL	15 min	CE
NEW IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE
NEW IF1052	PG I/PG II	Atrophic gastritis, stomach cancer	PG I <70.0 ng/mL PG I/PG II <3.0 ng/mL	S/P	PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL	100 μL	15 min	

Coming Soon: FOB, Folate...



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Web.: www.getein.com



FSC CE NMPA NGSP IFCC IVD



# Getein 1100

Immunofluorescence Quantitative Analyzer

User Manual





## Warnings, Precautions and Limitations

- a. Read this user manual carefully to obtain optimum performance from your analyzer.
- b. Only used for in vitro diagnostic analysis of human whole blood, plasma, serum, urine, stool and swabs.
- c. To avoid fire, electric shock or personal injuries, please turn off the power immediately and disconnect the power plug when any liquid seeps into the instrument, or the instrument leaks, emits smoke or a smell.
- d. Take proper safeguard measures in accordance with health and safety standards in the local country.
- e. Specimens and reagents may have potentially biological risks of infection. Operators should wear laboratory protective clothing and gloves required by the operation regulations of laboratory safety to avoid potential biological infection or contamination.
- f. All the test kits and consumables should be disposed of after a single use. Proper handling and disposal methods should be established by the laboratory director in accordance with local, status and federal regulations.
- g. Operators or person in charge shall be trained on cautions and operation instructions before operating the analyzer.
- h. If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

## Symbols & Description

	Manufacturer
	Date of manufacture
	Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i>
	Serial number
	<i>In Vitro</i> diagnostic medical device
	Catalogue number
	CE Mark
	Authorized representative in the European Community/European Union
	Warning
	Warning; Biological hazard
	This way up
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Stacking limit by number
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limit

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# 1.Introduction

## 1.1 Intended Use

Getein 1100 Immunofluorescence Quantitative Analyzer (hereinafter called Getein 1100) is an analyzer for processing Getein test kits and analysis of markers for cardiovascular diseases, renal diseases, inflammation, fertility, diabetes mellitus, bone metabolism, tumor and thyroid. This manual contains instructions for the use of Getein 1100 and general instructions for testing specimens and quality control materials.

## 1.2 Product Description

Getein 1100 is used to measure concentration of biomarkers in human whole blood, serum, plasma, urine, stool and swabs. The results can be used as an aid in clinical diagnosis of laboratory and point of care testing.

## 1.3 Product Principle

### 1.3.1 Overview: Running a Test

Apply sample (for example, serum) to the test card, insert the test card into Getein 1100 after a certain time (outside mode) or immediately (inside mode) and click the “Start” icon. Then the concentration of biomarkers in the sample will be measured and the result will be displayed (Fig.1-1). The test results can be transmitted to the lab or hospital information system (LIS or HIS) when the analyzer is connected to a computer.

Inside Mode (single sample rapid test mode)



Dispense sample

Insert test card

Click “Start”

Show and print result

Quick mode (mass samples rapid test mode)



Dispense sample

Time the reaction manually

Click “Start”







Show and print result

**Fig.1-1 Running a Test**

### 1.3.2 Working Principle

The detection element scans the binding area and converts the optical signal to electrical signal. The voltage variation between test line and background has a linear relationship with the antigen concentration which can be used to calculate the concentration. In conclusion, the antigen concentration in whole blood, plasma, serum, urine, stool and swabs can be calculated quantitatively according to the optical signal of the test line.

### 1.4 List of Icons

Icon	Name	Function
	Patient Information	Name, Gender, Age, Sample ID and Barcode can be edited here.
	Power Connection	Power is connected
	Battery	Built-in lithium battery.
	Search	Search results by name, sample ID or time.
	ON	Indicate the function is on.
	OFF	Indicate the function is off.

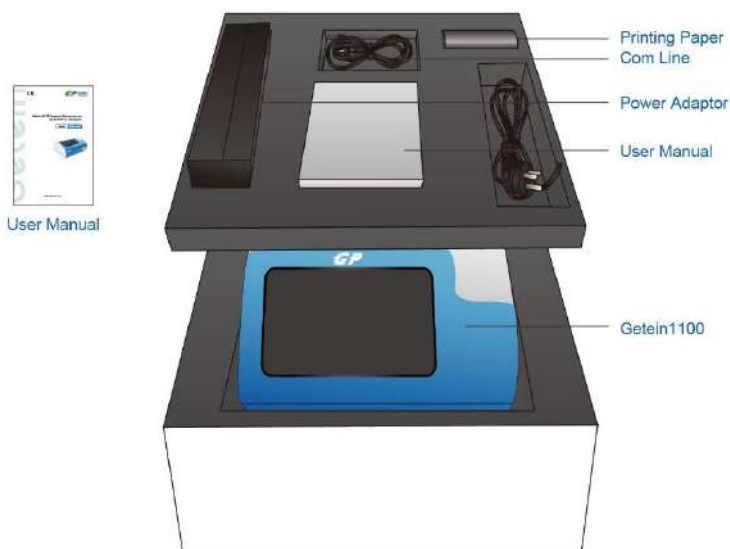
## 2.Installation

### 2.1 Unpacking

Check the analyzer and accessories with the packing list (Table 2-1). If you find any parts missing or any damages caused by improper transportation, contact your local agent or Getein's after-sales support immediately.

**Table 2-1 Getein 1100 Packing List**

No.	Description	Model	Unit	Quantity
1	Device	Getein 1100	set	1
2	Power Adapter	12 V 5 A	pc	1
3	Printing Paper	57 × 35 mm	pc	1
4	Data Cable		pc	1
5	User Manual (Device)		pc	1
6	Qualification Certificate & Warranty Card		pc	1
7	Lithium Battery	6.4 Ah	pc	Optional
8	Barcode Scanner		pc	Optional



**Fig.2-1 Getein 1100 and Main Accessories**



## 2.2 Analyzer Configuration

Getein 1100 is composed of control system, optical system, display unit, analog signal acquisition system, mechanical drive system, etc.

Front and rear view of Getein 1100 are shown in Fig.2-2 and Fig.2-3.



**Fig.2-2 Front View of Getein 1100**



**Fig.2-3 Rear View of Getein 1100**

## 2.3 Main Interface

### 1 Status Information

It mainly includes the status of power, battery and SD card, current date and time.

### 2 Test Information

It mainly includes patient information, test card information and result information.

### 3 System Menu

It mainly includes Test, Search and Settings.

Test: see details in 3.4.

Search: see details in 3.5.

Settings: see details in 4.1~4.7.

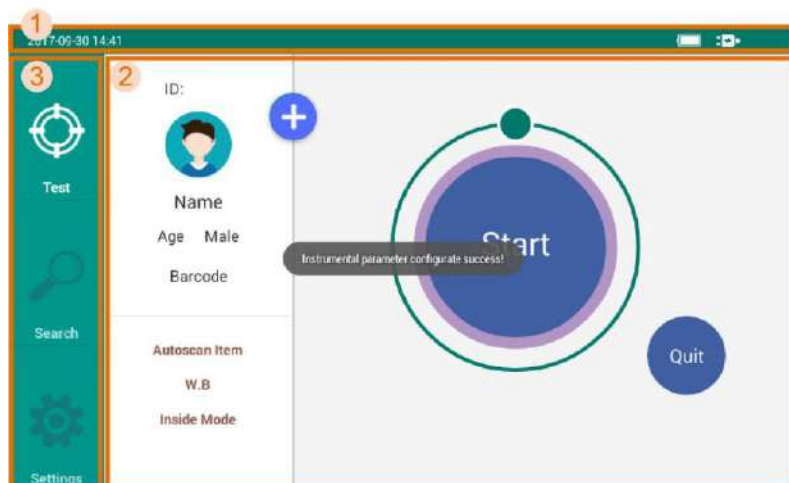


Fig.2-4 Main Interface

## 2.4 Performance Summary

### 2.4.1 Basic Parameters

Model	Operating Wavelength (nm)	Detection Range (mV)	Resolution (mV)
Getein 1100	635 ± 5	0 ~ 15000	1

### 2.4.2 Performance Indexes

<b>Blank Count</b>	Voltage of the blank QC card should be less than 100 mV
<b>Linearity</b>	$r \geq 0.95$ in the detection range from 0 mV to 15000 mV
<b>Repeatability</b>	CV ≤ 2% within range [100-15000] mV; CV ≤ 10% within range [0-100] mV
<b>Stability</b>	The voltage variation of the same standard card with a fixed concentration tested within 1 hour should be within ±10%

### 2.4.3 Technical Specifications

<b>Touch Screen</b>	7-inch LCD touch screen, 1024 × 600
<b>Communications</b>	Two USB ports for barcode scanning and software update COM port for PC Ethernet port for LIS

<b>Data Storage</b>	10,000 data	
<b>Dimensions</b>	261mm × 241mm × 115mm	
<b>Weight</b>	2.0 kg	
<b>Operating Environment</b>	Temperature	10°C ~ 35°C
	Relative humidity	≤ 70%
	Air pressure	70.0kPa ~ 106.0kPa
<b>Storage</b>	Temperature	-40°C ~ +55°C
	Relative humidity	≤ 93%
	Air pressure	50.0kPa ~ 106.0kPa
<b>Power Supply</b>	100 - 240V~ 50/60Hz 60VA	

## 2.5 Installation Requirements

### 2.5.1 Environment

Dry, clean, flat and horizontal surface away from direct sunlight, wind, hot source, noise source, power interferences, electronic brush type engine and mechanical vibration.

### 2.5.2 Space Requirement

Place Getein 1100 at a horizontal position and reserve enough space for the reagents.

## 2.6 Setup

### 2.6.1 Loading Paper

- 1) Open the printer cover.
  - 2) Place the printing paper into the printer with carbon sensitive surface facing the screen.
  - 3) Pull out approximate 5 cm of paper from the roll, and then close the cover.
- a). Open the printer cover      b). Load paper      c). Close the printer cover



Fig.2-5 Loading Paper

### 2.6.2 Barcode Scanner Connection (Optional)

Connect the barcode scanner via USB port in the lateral of the analyzer (see details in the instruction of scanner).

### 2.6.3 Lithium Battery (Optional)

- 1) The battery capacity can be shown by 4 icons. They are which represent low, medium, high and full power respectively.
- 2) The charging time of lithium battery is 6 hours and the battery can work for at least 3 hours (Note: The charging time and working time will change over time).
- 3) To avoid being affected by the low power and extend battery lifetime, please charge the analyzer when a low battery is indicated .

### 2.6.4 Power Connection

- 1) Use the adapter packed together with Getein 1100.  
Power supply: 100 - 240V~, Frequency: 50/60Hz
- 2) Connect power with Getein 1100 through the AC/DC adapter.
- 3) Press the power switch to turn on the analyzer.

## 3. Operation

### 3.1 Preparations before Power On

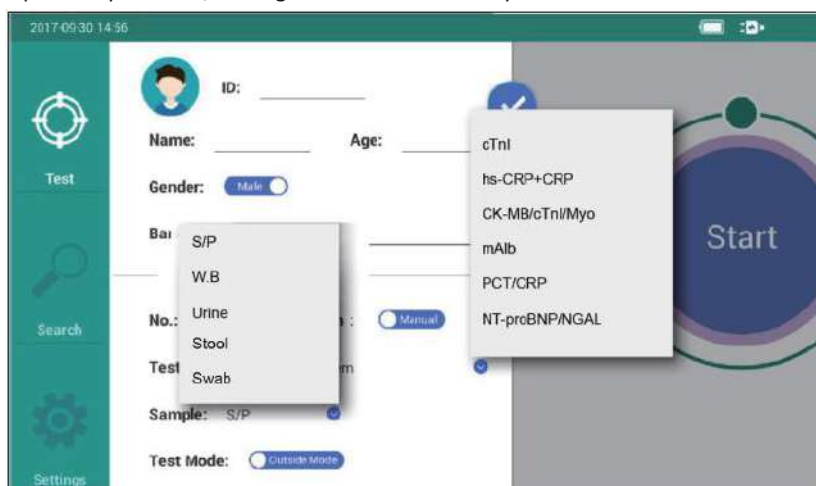
Please confirm whether the analyzer is ready for use according to the following steps before turning on the power switch.

- 1) Check whether the power supply is ready or connected safely.
- 2) Check whether the printing paper is enough and correctly loaded.

### 3.2 Power On

Press the switch to turn on the analyzer, and then system will start its self-checking and then enter the Test Interface.

Test Interface mainly includes Patient Information, Test Card Information and Result Information. Users can input patient information and select test item, sample and test mode as required (Fig.3-1). Barcode can be scanned through the scanner or inputted by the user; No. is generated automatically and cannot be modified.



**Fig.3-1 Test Interface**

### 3.3 SD Card Calibration

To guarantee the accuracy of measurement and the comparability of data, calibration is required before patient samples testing. Please use the corresponding SD card to calibrate the analyzer before testing different batches of kits (Note: SD card for different batches cannot be exchanged).

Steps: Attach the SD card to the SD card recognition zone, and the analyzer would show the prompt. Click "OK" to import the test card parameters (Fig.3-2).

Note: User can also insert the SD card into the SD card slot to do the calibration.

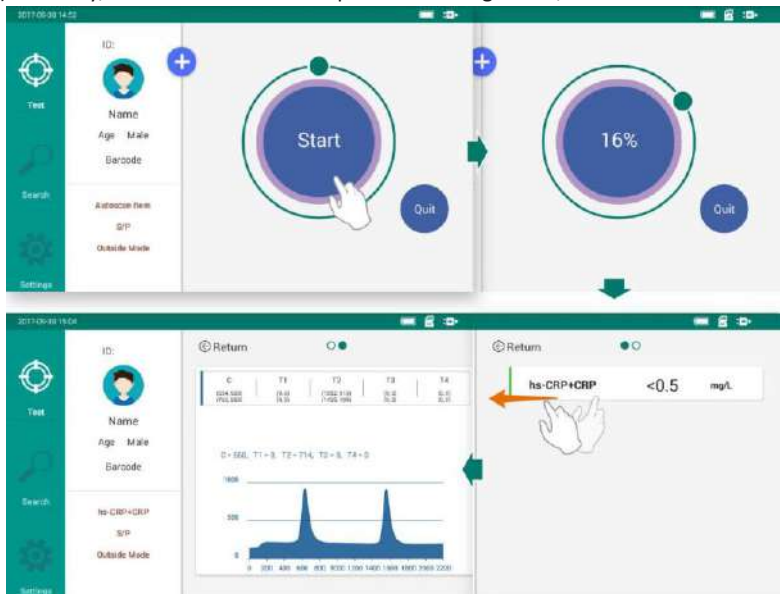


**Fig.3-2 SD Card Calibration**

### 3.4 Sample Test

User can perform sample test by the following steps (Fig.3-3):

- 1) Edit patient's information if needed.
- 2) Click "Start" after inserting the card. Test item will be auto-recognized and the result will be shown on the screen after the test is completed. Users can also see the voltage waveform by sliding to the left.
- 3) Normally, the test card will auto-quit after testing. If not, click the "Quit" icon.



**Fig.3-3 Sample Test**

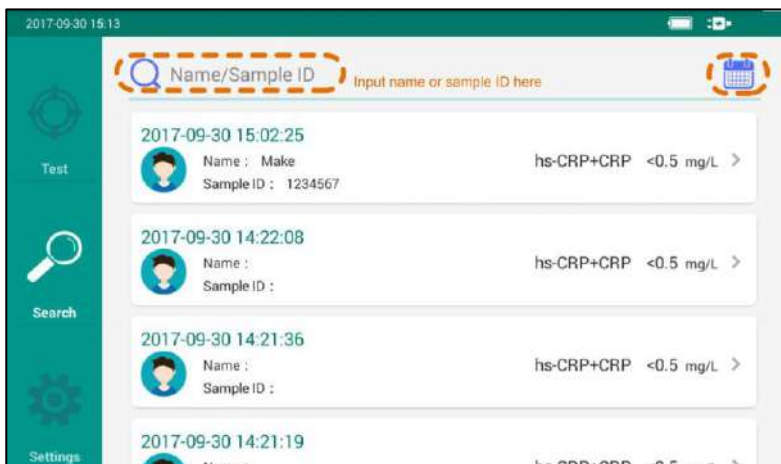
**Note:**

- 1) Do not switch the interfaces during the measurement.
- 2) Test items vary in sample volume and reaction time. Refer to the user manual of the specific item for accurate information.

## 3.5 Result Query

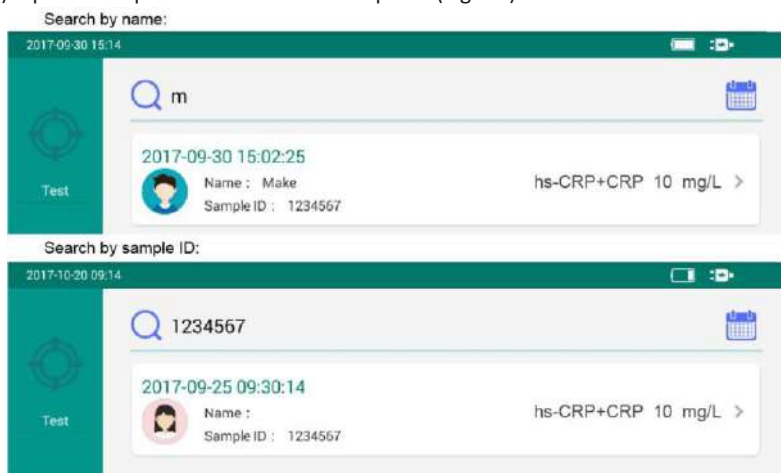
### 3.5.1 Query

Click the “Search” icon to switch to result query interface. There are three ways to query results (Fig.3-4).



**Fig.3-4 Query Interface**

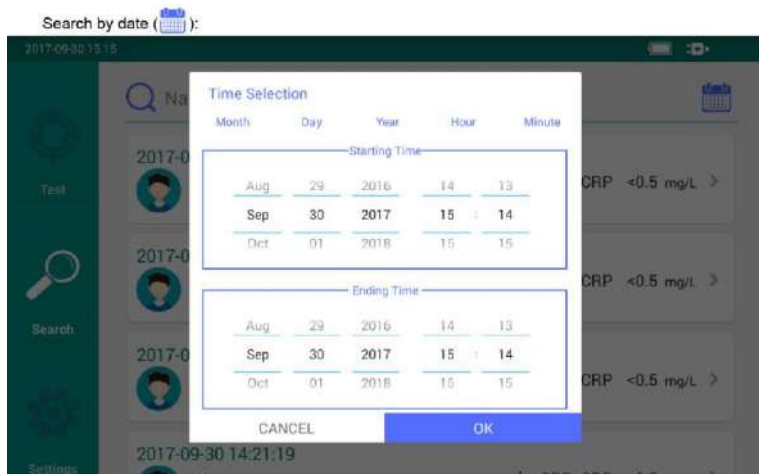
1) Input full or part of the Name or Sample ID (Fig.3-5).



**Fig.3-5 Search by Name and Sample ID**



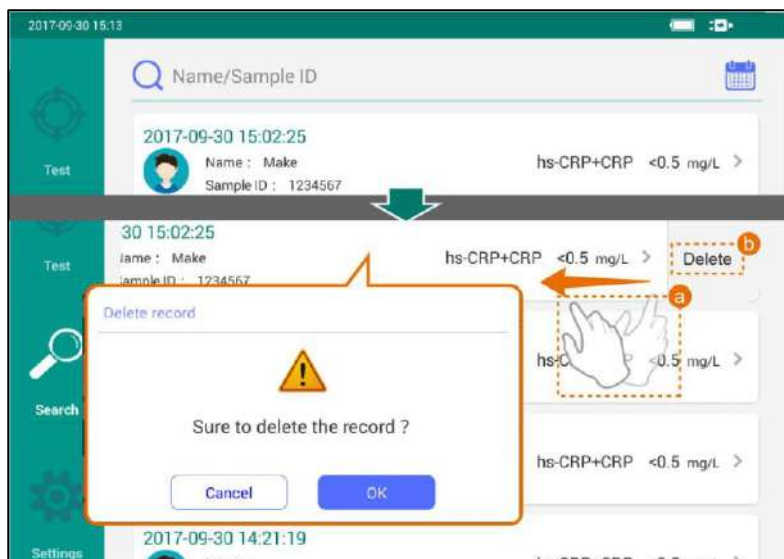
2) Select required Date & Time (Fig.3-6).



**Fig.3-6 Search by Date & Time**

### 3.5.2 Result Deletion

Select a result and slide it to the left. Click “Delete” and a prompt will be shown in the following interface (Fig.3-7). Then Click “OK” to delete it.



**Fig.3-7 Result Deletion**

### 3.5.3 Test Report

Click on the test result for the detailed test report (Fig.3-8). In the report interface, three icons “Print”, “Save” and “Upload” are listed. Slide to the left to view the test voltage waveform.

**Print:** click to print the test result.

**Save:** click to save the modifications.

**Upload:** click to transmit data to the information management system.

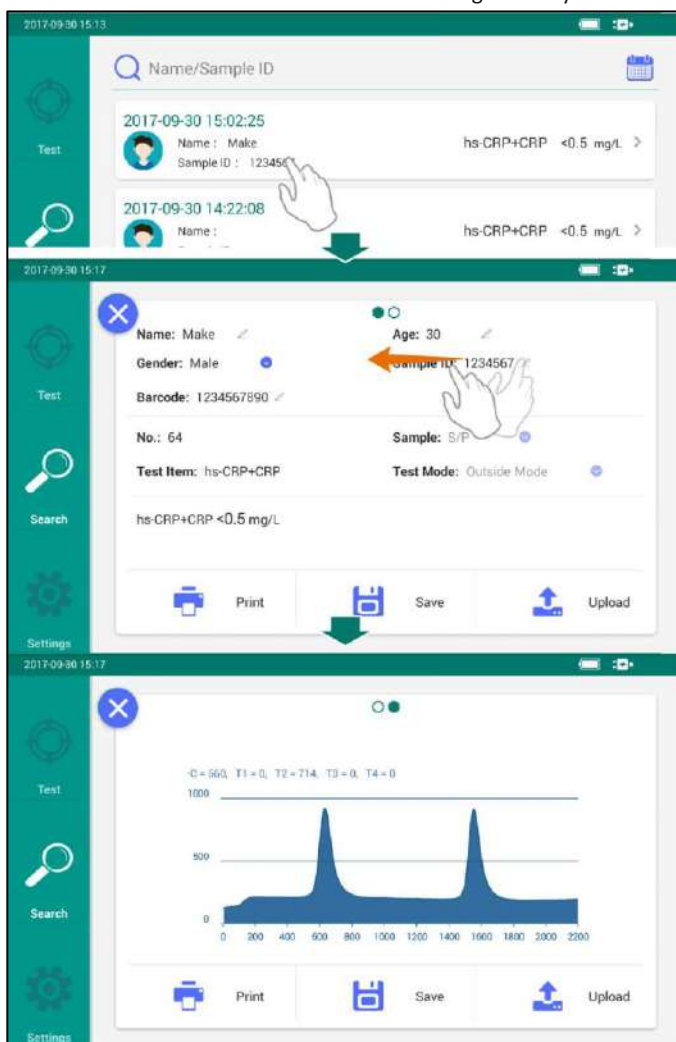


Fig.3-8 Test Report

Patient information is editable in case that user forgets to input or input wrong information. No., test item and result are not editable (Fig.3-9). Click the “Save” button after editing.

2017-09-30 15:18

Name: Make Age: 30

Gender: Male Sample ID: 1234567

Barcode: 1234567890

No.: 64 Sample: S/P

Test Item: hs-CRP+CRP Test Mode: Outside Mode

hs-CRP+CRP <0.5 mg/L

Save success!

Print Save Upload

**Fig.3-9 Edit Patient Information**

### 3.6 Shutdown

In any interface, user can press the switch to shut off the analyzer directly.

### 3.7 Waste Disposal

Liquid waste, used test cards, consumables and other wastes, including instrument at the end of life, are considered as medical waste, industrial waste or source of infection. Please handle them properly in accordance with local regulations.



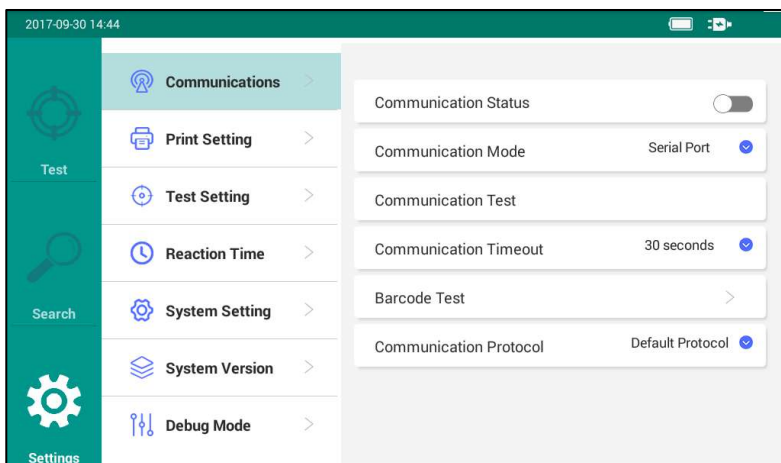
#### **Biological hazard**

- Follow and obey lab safety rules and guideline. Wear protective goggles, surgery gloves and laboratory coat to avoid the potential biological pollution risks.
- Disposal of medical wastes should be in accordance with the local regulations.

## 4.Settings

The installation and debugging of analyzer are performed before it leaves the factory. Operators can reset certain parameters in Settings to meet your laboratory's specific requirements.

Click the "Settings" icon to switch to the setting interface (Fig.4-1). There are 7 icons: Communications, Print Setting, Test Setting, Reaction Time, System Setting, System Version and Debug Mode.




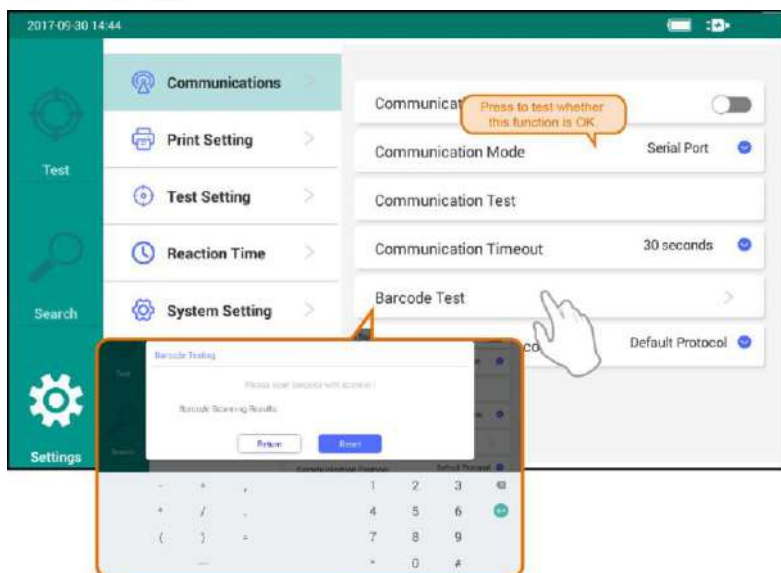
**Fig.4-1 Settings**

### 4.1 Communications Setting

It mainly includes Serial Port Status, Communication Mode, Communication Test, Communication Protocol, Communication Timeout and Barcode Test (Fig.4-2).

Note:

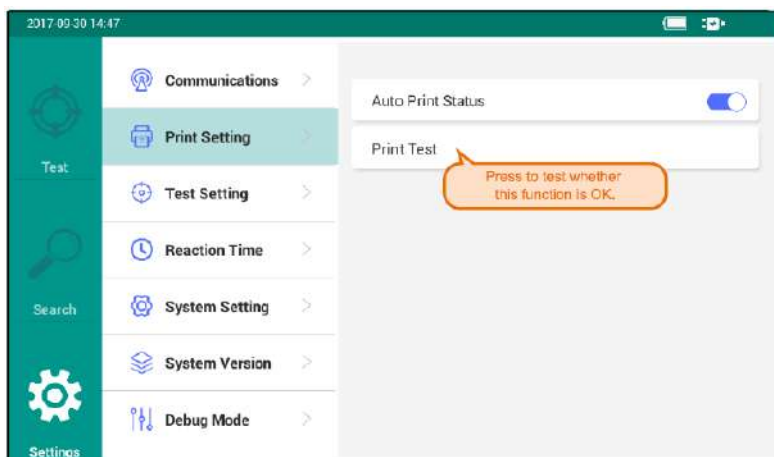
- Click "  " to the right of Communication Status to enable communication function; the system baud rate is 9600.
- Communication Mode includes Serial Port and WiFi.
- Click Communication Test to send test data through the selected serial port or Ethernet port
- Communication Timeout (10s, 30s, 1min and 5min) can be selected as the disconnection standard of Getein 1100 with the host computer.
- Click Barcode Test to perform barcode testing with a barcode scanner. The test result will be displayed in Barcode Testing.
- Communication Protocol should be selected by or with the assistance of after-sales personnel.



**Fig.4-2 Communications Setting**

## 4.2 Print Setting

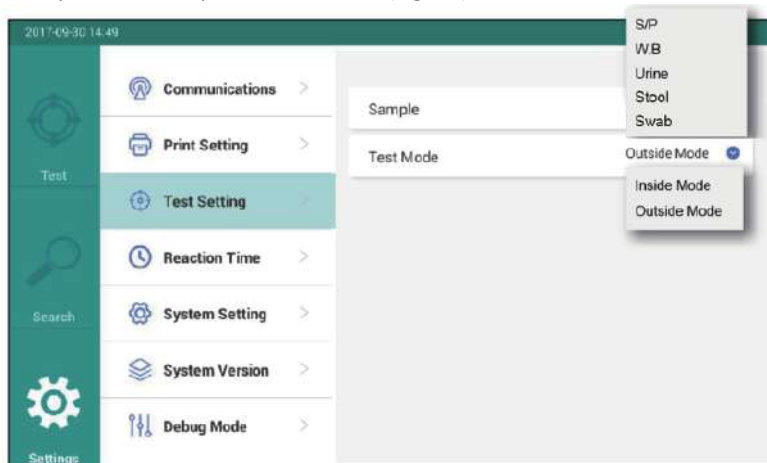
It mainly includes Auto Print Status and Print Test (Fig.4-3).



**Fig.4-3 Print Setting**

## 4.3 Test Setting

It mainly includes Sample and Test Mode (Fig.4-4).



**Fig.4-4 Test Setting**

## 4.4 Reaction Time

This interface displays the reaction time imported from SD card (Fig.4-5).

Note: Do not change the reaction time manually unless it is incorrect.

2017-09-30 14:49

Test

Search

Settings

Communications

Print Setting

Test Setting

Reaction Time

System Setting

System Version

Debug Mode

cTnI	S/P	10 min 0 sec
	W.B	10 min 0 sec
hs-CRP+CRP	S/P	3 min 0 sec
	W.B	3 min 0 sec
CK-MB/cTnI/Myo	S/P	10 min 0 sec
	W.B	10 min 0 sec
mAlb	Urine	3 min 0 sec

**Fig.4-5 Reaction Time**

## 4.5 System Setting

It mainly includes Screen Saver, Language, System Date/Time and Factory Reset (Fig.4-6).

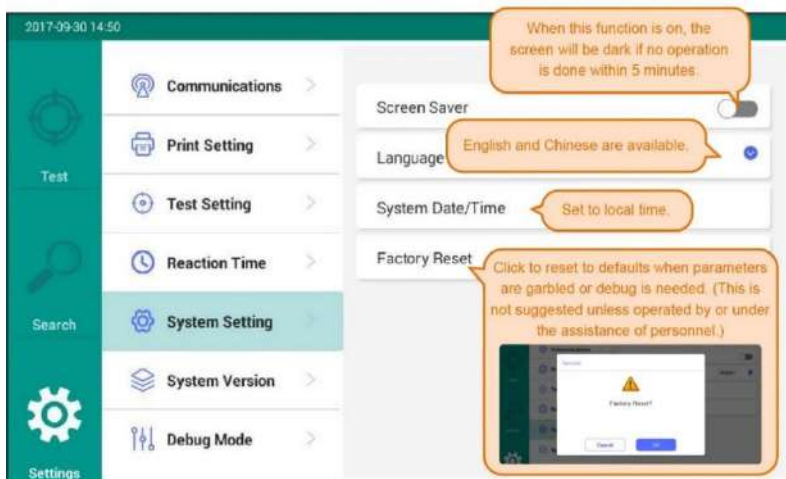


Fig.4-6 System Setting

## 4.6 System Version

In this interface, user can check the version of analyzer, serial number (SN) and the number of compatible assays (Fig.4-7).

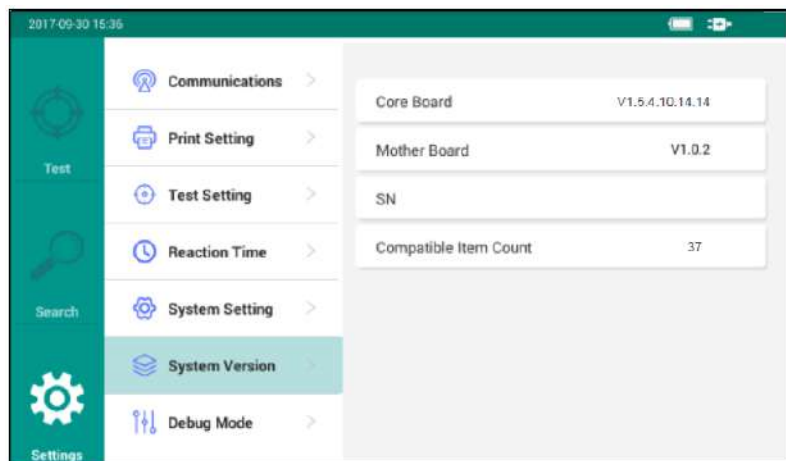
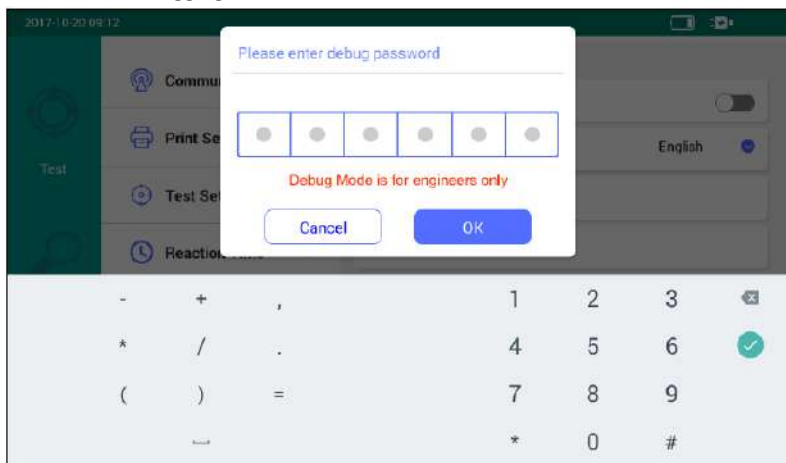


Fig.4-7 System Version



## 4.7 Debug Mode

Debugging functions are for Getein's after-sales support to debug the instrument. To avoid system parameters being modified by accident, users are not granted the access to the debugging interface.



**Fig.4-8 Debug Mode**

## 5. Maintenance and Troubleshooting

### 5.1 Maintenance

Getein 1100 requires minimal maintenance. Clean the surface with wet cloth and 70% ethanol (Turn off the analyzer and ensure the power plug is unconnected before cleaning in case of short circuit and electric shock). Do not clean any internal parts or inner surface. Strong bleach solution (0.5% or higher) is forbidden as oxidant solvent may damage the surface or the touch screen of analyzer.

Maintenance Item	Every Day	Every Week	Every Month	When needed
Dedusting		√		
SD Calibration				A new batch used
Replace Printing Paper				Printing paper used up
Replace LED Lamp				Light intensity weakened
Replace Lithium Battery				Battery damaged

### 5.2 Precautions

- 1) Please place the analyzer at a horizontal position for good operation.
- 2) Under power outage situation, please wait for 30 seconds before restarting the analyzer.
- 3) Only reagents supplied by Getein can be used on Getein 1100. Refer to the specific user manual for more details.
- 4) Preheat the analyzer for 20 minutes before testing to ensure the accuracy and reliability of results.
- 5) Dispose of the used test cards in accordance with the local regulations, as the sample and reagents may have potential risk of biological infections.
- 6) Please operate the analyzer according to the requirements of the instruction for long-term reliable work.
- 7) The personnel who operate the PC software should be familiar with the Windows XP, Windows 7 system together with the software installation and uninstallation.
- 8) Results will be stored automatically in the analyzer and can be recovered automatically after the analyzer is powered off. All data will be cleared if users select "Factory Reset" function.
- 9) Do not disassemble the analyzer. Operation done by laypeople may damage analyzer.
- 10) Please charge the analyzer when low battery is indicated.

## 5.3 Troubleshooting

If there is a malfunction during operating, alarm prompts will pop up.

Error	Cause	Solution
Invalid test card	No C line or shallow C line	Check the shelf life and test again with a new card
Sample type selection error	Inconsistent test item and sample type	Correct the sample mode, and re-test
Test item recognition error	SD card calibration not performed or barcode recognition failure	Do SD card calibration. Change a new card with a clear barcode
Lot error	Inconsistent test card with information stored in the analyzer	Re-calibration with the SD card (same Lot No. with the test card)

## 6. Appendix

### 6.1 Copyright

Getein Biotech, Inc.

Instrument Name: ImmunofluorescenceQuantitativeAnalyzer

Model: Getein 1100

Version: V3.1

Issue Date: 2023.11

### 6.2 Statement

- Getein Biotech Inc. owns the copyright to this non-published manual and has the right to take it as confidential information. This manual is provided for operation, maintenance and repair for Getein 1100 only. Anyone has no right to make this manual public.
- This manual contains proprietary information which is protected by copyright law. Copyright of this manual belongs to Getein Biotech Inc. Any content in this manual cannot be copied, reproduced or translated into other languages without the written consent of Getein.
- No warranties of any kind are made by Getein regarding this manual. Getein takes no responsibility for any consequential damages caused by errors in this manual.
- Getein holds the authority of the modification for contents of the manual without informing prior to it.

### 6.3 Manufacturer Responsibility

- Getein will only be responsible for instrument safety, reliability and performance in following cases: installation, upgrade, calibration, repair and maintenance are done by personnel assigned by Getein; users develop a regular maintenance plan and perform strictly.
- Hospitals or institutions who use this instrument should make a regular maintenance plan and perform strictly, otherwise inappropriate operations may lead to instrument failure or even endanger people's health.
- Getein will conditionally provide circuit diagram, calibration specifications and other documents required to assist the appropriate personnel to finish maintenance or repair under situations users can do themselves.
- Use only as directed. Getein will take no responsibility for protection failure of the analyzer caused by the analyzer being used in a manner not consistent with the instructions in this manual.

## 6.4 Analyzer Lifespan

The lifespan of Getein 1100 is 8 years (continuous working time no more than eight hours every day) under standardized operation and proper maintenance.



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Website: www.getein.com



### **CMC Medical Devices & Drugs S.L.**

Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Tel: +34951214054

***Pursue excellence***

***Deliver health***



# CERTIFICATE

*Getein Biotech*

hereby certifies

**Mr. Vitalie Goreacii**

**from Sanmedico SRL.**

**Completion of Getein Products Technical and Operational Training  
& Qualification of After-sales Service**

基蛋生物科技股份有限公司  
GETEIN BIOTECH, INC.





# cTnI Control

REF QC001

## User Manual

### PRODUCT NAME

cTnI Control

### PRODUCT SPECIFICATION

Package: 3(Level)\*2(Vial)\*1(ml), 3(Level)\*1(Vial)\*1(ml)  
cTnI Control - Level 1/2/3

### INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of Cardiac Troponin I (cTnI) on the Getein Platforms.

### PRINCIPLE

The lyophilized cTnI control is prepared from dissolving stable and high quality recombinant cTnI antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

### CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. cTnI Control - Level 1  
cTnI Control - Level 2  
cTnI Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. cTnI Control - Level 1  
cTnI Control - Level 2  
cTnI Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box
4. Quality control holder - Level 1  
Quality control holder - Level 2  
Quality control holder - Level 3

**Note:** Each quality control holder is labelled with barcode which contains target value and level of different items.

### MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer  
Getein1100/1600 Immunofluorescence Quantitative Analyzer

### STORAGE AND STABILITY

**UNOPENED:** The product is stable for 18 months at -20°C and for 30 days at 2 ~ 8°C to avoid light.

**OPENED:** The product is stable for 1 day at 2 ~ 8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70°C.

### MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

### TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30°C) prior to use.
2. Open the vial carefully in case of the loss of content.
3. Dissolve each control material with 1 ml distilled water.

4. Close the vial and mix gently until all contents are dissolved completely. Avoid violent shaking or foam formation.
5. Keep it at room temperature for 5 ~ 10 minutes before use.  
For FIA8000/FIA8600/Getein1100:
6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

## ASSIGNED VALUES

Refer to values listed on the target value sheet.  
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.  
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

## PERFORMANCE CHARACTERISTICS

1. Homogeneity:  $\leq 15\%$
2. Accuracy range: Refer to the target value sheet

## LIMITATIONS













1. This product can only be used on the Getein Platforms.
2. Variation exists between different equipments developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.

## NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.
5. Proper handling and disposal methods should be followed in accordance with local regulations.

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on cTnI control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
	Catalogue number		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Biological risk
	CE mark		Authorized representative in the European Community

Please read this user manual carefully before operating to ensure proper use.

Version: WZK01-S-04



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Please contact Getein if you have any questions.



# D-Dimer Control

REF QC006

User Manual

## PRODUCT NAME

D-Dimer Control

## PRODUCT SPECIFICATION

Package: 3(Level)\*2(Vial)\*1(ml), 3(Level)\*1(Vial)\*1(ml)  
D-Dimer Control - Level 1/2/3

## INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of D-Dimer on the Getein Platforms.

## PRINCIPLE

The lyophilized D-Dimer control is prepared from dissolving stable and high quality recombinant D-Dimer antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

## CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. D-Dimer Control - Level 1  
D-Dimer Control - Level 2  
D-Dimer Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. D-Dimer Control - Level 1  
D-Dimer Control - Level 2  
D-Dimer Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box
4. Quality control holder - Level 1  
Quality control holder - Level 2  
Quality control holder - Level 3

**Note:** Each quality control holder is labelled with barcode which contains target value and level of different items.

## MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer  
Getein1100/1600 Immunofluorescence Quantitative Analyzer

## STORAGE AND STABILITY

**UNOPENED:** The product is stable for 18 months at -20°C and for 90 days at 2 ~ 8°C to avoid light.

**OPENED:** The product is stable for 15 days at 2 ~ 8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70°C.

## MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

## TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30°C) prior to use.
2. Open the vial carefully in case of the loss of content.

3. Dissolve each control material with 1 ml distilled water.
4. Close the vial and mix gently until all contents are dissolved completely. Avoid violent shaking or foam formation.
5. Keep it at room temperature for 5 ~ 10 minutes before use.  
For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

## ASSIGNED VALUES

Refer to values listed on the target value sheet.

If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.

The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

## PERFORMANCE CHARACTERISTICS

1. Homogeneity:  $\leq 15\%$
2. Accuracy range: Refer to the target value sheet

## LIMITATIONS

1. This product can only be used on the Getein Platforms.
2. Variation exists between different equipments developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.













## NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.

5. Proper handling and disposal methods should be followed in accordance with local regulations.

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
	Catalogue number		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Biological risk
	CE mark		Authorized representative in the European Community

Please read this user manual carefully before operating to ensure proper use.

Version: WZK04-S-04



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## hs-CRP Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1003

Getein1600: Cat.# IF2003

### User Manual

### INTENDED USE

hs-CRP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of C-reactive protein (CRP) in serum, plasma whole blood, or fingertip blood. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury and inflammatory disorders. Measurement of high sensitivity CRP (hs-CRP), when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes (ACS), may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or ACS.

### SUMMARY

C-reactive protein is an acute-phase reactant that precipitated with Pneumococcal C-polysaccharide, and is a non-specific immune response component. CRP has wide distribution in our body, and is an acute-phase protein produced in the liver in response to microbic infection or tissue injury, and the hs-CRP can be used to detect lower concentrations of CRP in serum or plasma. Studies revealed hs-CRP levels seem to be correlated with Atherosclerosis and Acute Myocardial Infarction. And the hs-CRP is an inflammation "marker" for ACS patient and is helpful for primary prevention and risk assessment of cardiovascular disease. Its combination with the ratio of total cholesterol to HDL-C is more accurate than other risk factor in predicting cardiovascular disease.

The American Heart Association and US Centers for Disease Control and Prevention have advocated hs-CRP as a predictor of cardiovascular disease (CVD) to define risk groups: less than 1.0 mg/L indicates low risk, 1.0 to 3.0 mg/L means moderate risk, and the amount above 3.0 mg/L (lower than 10 mg/L) strongly suggests a high risk of CVD. Moreover, higher CRP levels are found in late pregnant women, mild inflammation and viral infections (10~40 mg/L), active inflammation, bacterial infection (40~200 mg/L), severe bacterial infections and burns

(>200 mg/L).

### PRINCIPLE

The test uses an anti-human hs-CRP monoclonal antibody conjugated with fluorescence latex and another anti-human hs-CRP monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human hs-CRP monoclonal antibody binds with the hs-CRP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human hs-CRP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of hs-CRP in sample. Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of hs-CRP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

### CONTENTS

#### 1. A kit for Getein1100 contains:

Getein hs-CRP test card in a sealed pouch with desiccant .....	25
Disposable pipet .....	25
Sample diluent .....	25
SD card .....	1
User manual .....	1

#### 2. A kit for Getein1600 contains:

Sealed cartridge with 24/48 Getein hs-CRP test cards ..	2
User manual .....	1
<u>Package specifications:</u>	
2×24 tests/kit, 2×48 tests/kit	
<u>Materials required for Getein1600:</u>	
Sample diluent .....	1
Box with pipette tips .....	1
Mixing plate .....	1

#### 3. Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

#### 4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human hs-CRP monoclonal antibody, the test line is coated

with another anti-human hs-CRP monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

**Note: Do not mix or interchange different batches of kits.**

### APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

### STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

### PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

### SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *serum, plasma, whole blood and fingertip blood samples*. *Heparin, sodium citrate and EDTA* can be used as the anticoagulant for plasma, whole blood and fingertip blood. Samples should be free of hemolysis.



- 2. Suggest using serum or plasma for better results.
- 3. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2-8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2-8°C).
- 4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- 5. Do not use heat-inactivated samples.
- 6. SAMPLE VOLUME (for Getein1100): 10 µl.

TEST PROCEDURE

- 1. Collect specimens according to user manual.
  - 2. Test card, sample and reagent should be brought to room temperature before testing.
- For Getein1100:
- 3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
  - 4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
  - 5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
  - 6. Put the test card on a clean table, horizontally placed.
  - 7. Using sample transfer pipette, deliver 10 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3-4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
  - 8. Reaction time: 3 minutes. Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

- 9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- 10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

- 1. It is required to perform "SD Card Calib" calibration when using a new batch of kits.
- 2. It is suggested to calibrate once for one batch of kits for Getein1100.
- 3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

hs-CRP: The expected normal value for hs-CRP was determined by testing samples from 500 apparently healthy individuals. The 95<sup>th</sup> percentile of the concentration for hs-CRP is 3 mg/L. (The probability that hs-CRP value of a normal person below 3 mg/L is 95%.)

CRP: The expected normal value for CRP was determined by testing samples from 500 apparently healthy individuals. The 95<sup>th</sup> percentile of the concentration for CRP is 10 mg/L. (The probability that CRP value of a normal person below 10 mg/L is 95%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.5~200 mg/L
Lower Detection Limit	≤0.5 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with HITACHI 7600/OLYMPUS AU5400 and its matching hs-CRP test kits with 200 serum samples (61 positive samples and 139 negative samples). The correlation coefficient (r) for hs-CRP is 0.941.

LIMITATIONS

- 1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- 2. Samples containing interferences may influence the results. The table below listed the maximum allowance of these potential interferences.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	10 g/L	0.2 g/L

REFERENCES

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- 2. Rifai N, Ridker PM. Proposed cardiovascular risk assessment algorithm using high-sensitivity C-reactive protein and lipid screening. Clin Chem 2001; 47:28~30.
- 3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- 4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on hs-CRP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing hs-CRP Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF04-S-02

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# Cardiac Troponin I

## Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1001

Getein1600: Cat.# IF2001

### User Manual

## INTENDED USE

Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cardiac Troponin I (cTnI) in serum, plasma or whole blood. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

## SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarction (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

The current guideline of The Joint European Society of Cardiology/ American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current

guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

## PRINCIPLE

The test uses an anti-human cTnI monoclonal antibody conjugated with fluorescence latex and another anti-human cTnI monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human cTnI monoclonal antibody binds with the cTnI in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human cTnI monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of cTnI in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of cTnI in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

## CONTENTS

- A kit for Getein1100 contains:
  - Getein cTnI test card in a sealed pouch with desiccant ..... 25
  - Disposable pipet ..... 25
  - Whole blood buffer ..... 1
  - SD card ..... 1
  - User manual ..... 1
- A kit for Getein1600 contains:
  - Sealed cartridge with 24/48 Getein cTnI test cards ..... 2
  - User manual ..... 1
  - Package specifications:
  - 2x24 tests/kit, 2x48 tests/kit
  - Materials required for Getein1600:
  - Sample diluent ..... 1
  - Box with pipette tips ..... 1
  - Mixing plate ..... 1
- Sample diluent/Whole blood buffer composition:
  - Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
- A test card consists of:
  - A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-

human cTnI monoclonal antibody, the test line is coated with another anti-human cTnI monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

**Note: Do not mix or interchange different batches of kits.**

## APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer  
Getein1600 Immunofluorescence Quantitative Analyzer

## STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

## PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Do not reuse the test card.
- Do not reuse the pipet.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow user manual to ensure proper test performance.

## SPECIMEN COLLECTION AND PREPARATION

- This test can be used for *serum, plasma and whole blood samples*. *Heparin and sodium citrate* should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.

- Suggest using serum or plasma for better results.
- Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
- If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME (for Getein1100): 100 µl.

### TEST PROCEDURE

- Collect specimens according to user manual.
- Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
- On the main interface of Getein1100, press "ENT" button to enter testing interface.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver 100 µl of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
- Reaction time: 10 minutes. Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

- Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

#### Notes:

- It is required to perform "SD Card Calib" calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein1100.
- Make sure the test card and the sample insertion is correct and complete.

### TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

### EXPECTED VALUE

The expected normal value for Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99<sup>th</sup> percentile of the concentration for cTnI is 0.1 ng/mL. (The probability that value of a normal person below 0.1 ng/mL is 99%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

### PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~50 ng/mL
Lower Detection Limit	≤ 0.1 ng/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with SIEMENS IMMULITE 2000 and its matching cTnI test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for cTnI is 0.952.

### LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

### REFERENCES

- Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
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Guidelines (Committee to Revise the 1999 Guidelines for the Management 2004).

- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

### DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF02-S-02



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## D-Dimer Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1006

Getein1600: Cat.# IF2006

### User Manual

## INTENDED USE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of D-Dimer in plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of deep-vein thrombosis or pulmonary embolism.

## SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

## PRINCIPLE

The test uses an anti-human D-Dimer monoclonal antibody conjugated with fluorescence latex and another anti-human D-Dimer monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human D-Dimer monoclonal antibody binds with the D-Dimer in sample and forms a marked antigen-antibody

complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another anti-human D-Dimer monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of D-Dimer in sample. Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

## CONTENTS

- A kit for Getein1100 contains:
 

Getein D-Dimer test card in a sealed pouch with desiccant .....	25
Disposable pipet .....	25
Sample diluent .....	25
SD card .....	1
User manual .....	1
- A kit for Getein1600 contains:
 

Sealed cartridge with 24/48 Getein D-Dimer test cards .....	2
User manual .....	1

Package specifications:  
 2×24 tests/kit, 2×48 tests/kit  
Materials required for Getein1600:

Sample diluent .....	1
Box with pipette tips .....	1
Mixing plate .....	1
- Sample diluent composition:
 

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
- A test card consists of:
 

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human D-Dimer monoclonal antibody, the test line is coated with another anti-human D-Dimer monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

**Note: Do not mix or interchange different batches of kits.**

## APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer  
 Getein1600 Immunofluorescence Quantitative Analyzer

## STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

## PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Do not reuse the test card.
- Do not reuse the pipet.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow user manual to ensure proper test performance.

## SPECIMEN COLLECTION AND PREPARATION

- This test can be used for *plasma and whole blood samples*. *Sodium citrate* can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using plasma for better results.
- If testing will be delayed, plasma sample may be stored up to 3 days at 2~8°C or stored at -20°C for 1 month before testing (whole blood sample may be stored up to 3 days at 2~8°C).
- Refrigerated or frozen sample should reach room temperature

and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

- Do not use heat-inactivated samples.
- SAMPLE VOLUME (for **Getein1100**): 100 µl.

## TEST PROCEDURE

- Collect specimens according to user manual.
- Test card, sample and reagent should be brought to room temperature before testing.

### For Getein1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
- On the main interface of Getein1100, press "ENT" button to enter testing interface.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver 100 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3-4 drops of sample when using disposable pipet) into the sample port on the test card.
- Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

### For Getein1600:

- Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

### **Notes:**

- It is required to perform "SD Card Calib" calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein1100.
- Make sure the test card and the sample insertion is correct and complete.

## TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

## EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95<sup>th</sup> percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)

It is recommended that each laboratory establish its own expected values for the population it serves.

## PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~10.0 mg/L
Lower Detection Limit	≤0.1 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

### Method Comparison:

The assay was compared with SIEMENS CA-7000 and its matching D-Dimer test kits with 200 plasma samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

## LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

## REFERENCES













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- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing D-Dimer Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF05-S-02



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Website: www.bio-GP.com.cn





浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co.,LTD

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## STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21



*[Handwritten signature in blue ink]*

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# Certificate

No. Q5 092305 0001 Rev. 01

**Holder of Certificate:** **Zhejiang Orient Gene Biotech Co., Ltd.**  
3787#, East Yangguang Avenue, Dipu Street Anji  
313300 Huzhou, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

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 092305 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01)

**Report No.:** SH2198802

**Valid from:** 2022-04-11

**Valid until:** 2024-03-16

**Date,** 2022-04-11

Christoph Dicks

Head of Certification/Notified Body

# Certificate

No. Q5 092305 0001 Rev. 01

**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):**

Zhejiang Orient Gene Biotech Co., Ltd.  
3787#, East Yangguang Avenue, Dipu Street Anji, 313300  
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** Healgen Scientific Limited Liability Company

**Legal Manufacturer Address:** 3818 Fuqua Street, Houston, TX 77047, USA.

Declares, that the products  
Product Name and Model(s)

Orient Gene HCV Hepatitis C Virus Rapid Test (Serum/Plasma) (Cassette)	GCHCV-302a
Orient Gene HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)	GCHCV-402a

EDMA Code: 15 70 02 02

**Classification:** Annex II List A  
**Conformity assessment route:** Annex IV (Full Quality Assurance)

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

**Notified Body:** TÜV SÜD Product Service GmbH

**Notified Body Address:** Munich Branch Ridlerstraße 65 80339 München Germany

**EC Certificate No.:** V1 092378 0004 Rev. 02 Valid until: 2025-05-26

**EC Design-Examination Certificate No.:** V7 092378 0009 Rev. 00 Valid until: 2025-05-26

It bears the mark

**CE 0123**

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

**EC Representative Name:** QARAD b.v.b.a.

**EC Representative Address:** Cipalstraat 3, B-2440 Geel, Belgium

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Signature: 

Name of authorized signatory: Joyce Pang

Position held in the company: Vice-President

Date: 2022.4.22



Zhejiang Orient Gene Biotech Co., LTD

## CERTIFICATE OF ANALYSIS

Product Name: HBsAg Rapid Test (Whole blood/Serum/Plasma) (Cassette)

Catalog NO.: GCHBsg-402a

Purchase NO.: 2023-IEU157#

Lot NO.: 2310203

Quantity: 3000pcs

Expiration Date: 2025.09

CONTROLS		SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens		Negative	Negative	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Specimens	1ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	2ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	3ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	5ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

Conclusion: ☒Pass: All results meet QC standard.  
☐Fail

Test by:

QC Supervisor:

Date:

2023.10.28



**Zhejiang Orient Gene Biotech Co., LTD**

## **CERTIFICATE OF ANALYSIS**

**Product Name:** HBcAb Rapid Test (Whole blood Serum Plasma) (Cassette)

**Catalog NO.:** GCHBcB-402a

**Purchase NO.:** 2023-SI156#

**Lot NO.:** S2303140

**Quantity:** 50 pcs

**Expiration Date:** 2025 02

CONTROLS	SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens	Negative	Negative	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Specimens	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

**Conclusion:** ☒Pass: All results meet QC standard.

☐Fail

**Test by:**

查妍

**QC Supervisor:**

雷伙愚

**Date:** 2023.03.28

# HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma)

## INTENDED USE

The HBsAg Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Hepatitis B virus (HBV). Any reactive specimen with the HBsAg Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

## INTRODUCTION

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus. The HBsAg Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma specimens. The test utilizes a combination of double monoclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

## PRINCIPLE

The HBsAg Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, Hepatitis B Surface Antigen in the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that the proper volume of specimen has been added and membrane wicking has occurred.

## PRODUCT CONTENTS

The HBsAg Test Cassette (Whole Blood/Serum/Plasma) containing anti-HBsAg antibodies particles and anti-HBsAg antibodies coated on the membrane.

## MATERIALS SUPPLIED

1. Test Cassette
2. Desiccant
3. Pipette Dropper
4. Buffer
5. Package Insert

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

## STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

## WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.

4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. electric fan or strong air conditioning.

## SPECIMEN COLLECTION

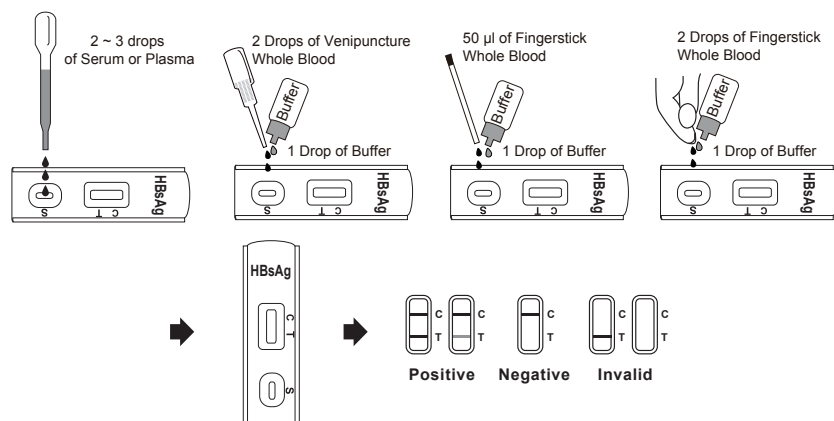
1. HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
  - Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:
    - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

**Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.  
**For Serum or Plasma Specimens:** Hold the dropper vertically and transfer 2-3 drops of serum or plasma (approximately 60-90 µL) to the specimen well (S) of the test device. See illustration below.  
**For Venipuncture Whole Blood Specimens:** Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.  
**For Fingerstick Whole Blood Specimens:** Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.

# HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma)



## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE:** Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

**NEGATIVE:** One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. Though the HBsAg Rapid Test Cassette is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.
2. The HBsAg Rapid Test Cassette is limited to the qualitative detection of HBsAg in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with HBsAg titer in the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with HBV. Infection through recent exposure (seroconversion) to HBV may not be detectable.
4. A negative result can occur if the quantity of HBsAg present in the specimen is below the detection limits of the assay (lower than 1 ng/mL), or the HBsAg that are detected are not present during the stage of disease in which a sample is collected.
5. Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
6. This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.

7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## PERFORMANCE CHARACTERISTICS

### Sensitivity:

The HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma). The test can detect 5ng/mL of HBsAg in 10 minutes, and 1 ng/mL of HBsAg in 15 minutes.

### Specificity:

Antibodies used for the HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

### HBsAg Rapid Test Cassette vs. EIA test

Method		EIA		Total Results
HBsAg Rapid Test Cassette	Results	Positive	Negative	
	Positive	345	5	350
	Negative	2	980	982
Total Results		347	985	1332

Relative sensitivity: 99.4%

Relative specificity: 99.5%

Accuracy: 99.5%

## REFERENCE

1. Blumberg, B. S. The Discovery of Australian Antigen and its relation to viral hepatitis. *Vitro*. 1971; 7: 223



# HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

## INTENDED USE

The HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- Hepatitis C virus (HCV) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Ab Rapid Cassette must be confirmed with alternative testing method(s) and clinical findings.

## INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens <sup>(1, 2)</sup>. Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests <sup>(3, 4)</sup>.

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in whole blood, serum or plasma.

## PRINCIPLE

The HCV Ab Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG–gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG–gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another device.

## PRODUCT CONTENTS

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) containing HCV antigen coated particles and HCV antigen coated on the membrane.

## MATERIALS SUPPLIED

1. Test Strip   2. Pipette Dropper   3.Desiccant   4.Buffer   5.Package Insert

## MATERIAL REQUIRED BUT NOT PROVIDED

1.Specimen collection containers                      2.Lancets (for fingerstick whole blood only)  
3.Centrifuge (for plasma only)                        4.Timer  
5.Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

## STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

## WARNINGS AND PRECAUTIONS

1.For professional In Vitro diagnostic use only. Do not use after expiration date.  
2.Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to

prevent azide build-up.

3. Do not use it if the tube/pouch is damaged or broken.

4.Test is for single use only. Do not re-use under any circumstances.

5.Handle all specimens as if they contain infectious agents.Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.

6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

7. Humidity and temperature can adversely affect results .

## SPECIMEN COLLECTION

1.The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

2.To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

- Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.

- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

- Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:

- Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.

- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.

- Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:

- Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.

- Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device or, move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

4.Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

5.Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

6.If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

**Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

1.Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface.

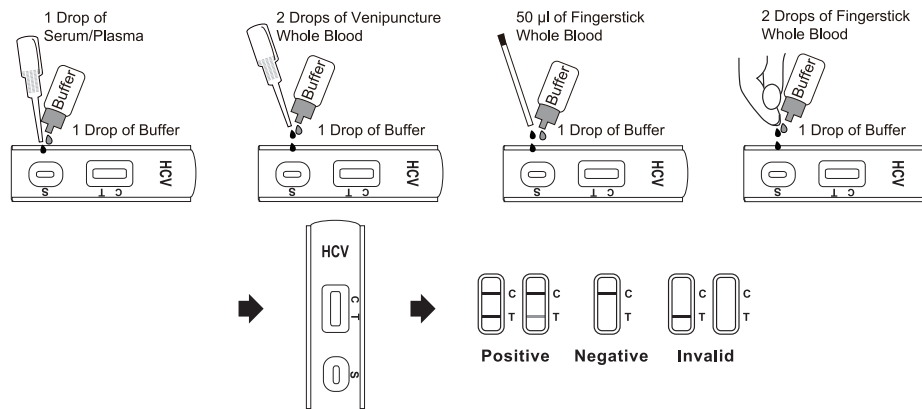
**For Serum or Plasma Specimens:** Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

**For Venipuncture Whole Blood Specimens:** Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

**For Fingerstick Whole Blood Specimens:** Allow 2 hanging drops of fingerstick whole blood (approximately 50 µ L) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µ L) and start the timer. See illustration below.

# HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



## INTERPRETATION OF RESULTS

(please refer to the illustration above)

**Positive:** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

**Negative:** One colored line appears in the control line region (C). No line appears in the test line region (T).

**Invalid:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

## LIMITATIONS

1. The HCV Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
2. The HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
5. A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

## PERFORMANCE CHARACTERISTICS

**Sensitivity:** HCV Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) has passed a seroconversion panel and compared with leading commercial HCV EIA test using clinical specimens.

**Specificity:** The recombinant antigens used for HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) are encoded by genes for both structural (nucleocapsid) and non-structural proteins. HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is highly specific for antibodies to Hepatitis C Virus compared with a leading

commercial HCV EIA test.

### The HCV Ab Rapid Test Cassette vs EIA test

Method		EIA		Total Results
HCV Ab RapidTest	Results	Positive	Negative	
	Positive	105	19	
	Negative	2	1760	
Total Results		107	1779	1886

Relative sensitivity: 98.1%

Relative specificity: 98.9%

Accuracy: 98.9%

## REFERENCE

1. Choo, Q.L., G.Kuo,A.J. Weiner, L.R. Overby,D.W. Bradley, andM. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome Science 189;244:359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiolog Virus of human non-A, non-B hepatitis. Science 1989; 244:362.
3. Van der Poel, C.L., H.T.M. Cuypers, H.W. Reesink, and P.N. Lelie .Confirmation of hepatitis C Virus infection by new four- antigen recombinant immunoblot assay. Lancet 1991;337:317
4. Wilber, J.C.Development and use of laboratory tests for hepatitis C infection: a review.J. Clin. Immunoassy 1993;16:204.

# Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma)

A rapid, one step test for the qualitative detection of Hepatitis B Core Antibody (HBcAb) in whole blood, serum or plasma. It is for professional in vitro diagnostic use only.

## INTENDED USE

The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid, one step test for the qualitative detection of Hepatitis B Core Antibody (HBcAb) in whole blood, serum or plasma.

## SUMMARY

Chronic hepatitis B is a serious, debilitating illness that can cause cirrhosis of the liver, liver cancer and death. Chronic hepatitis B is the main cause of liver cancer and the tenth leading cause of death worldwide, with 400,000,000 people infected with the virus. Every year, one million people worldwide are expected to die from this infection. Most people fight off the infection themselves, but approximately 5-10 percent of those infected with the virus become carriers, and an additional 5-10 percent of those infected each year will progress to chronic liver disease, cirrhosis and possibly liver cancer. The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBcAb in whole blood, serum or plasma without the use of an instrument.

## PRINCIPLE

Hepatitis B Core Antibody (HBcAb) is also known as anti-Hepatitis B core Antigen (anti-HBc). These tests are immunoassays based on the principle of competitive binding. During testing, the mixture migrates upward on the membrane chromatographically by capillary action. The membrane is pre-coated with HBcAg on the test line region of the strip. During testing, anti-HBc antibody, if present in the specimen, will compete with particle coated anti-HBc antibody for limited amount of HBcAg on the membrane, and no line will form in the test line region, indicating a positive result. A visible colored line will form in the test line region if there is no anti-HBc antibody in the specimen because all the antibody coated particles will be captured by the antigen coated in the test line region. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

## MATERIALS SUPPLIED

Test cassette	Dropper	Buffer	Package insert
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## MATERIAL REQUIRED BUT NOT PROVIDED

Specimen collection container	Centrifuge (for plasma only)	Timer
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## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The

test must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

## WARNINGS AND PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

## SPECIMEN COLLECTION AND PREPARATION

1. The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
2. To collect venipuncture whole blood specimens: Collect anti-coagulated blood sample (EDTA-K2, heparin, and sodium citrate) following standard laboratory procedures.
3. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, no hemolyzed specimens can be used.
4. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.

## TEST PROCEDURE

**Allow test device, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

### For Serum or Plasma:

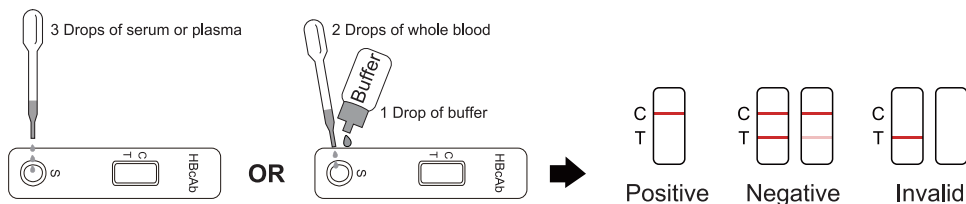
Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 75 µL) to each specimen well (S) of the test cassette respectively, avoid trapping air bubbles in the specimen well (S). See illustration below.

### For Venipuncture Whole Blood specimens:

Hold the dropper vertically and transfer 2 drops of whole blood (approx. 50 µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 40 µL) and starts the time. See illustration below.



- Wait for the red line(s) to appear. The results should be read at 15 minutes. Do not interpret the results after 20 minutes.



### INTERPRETATION OF RESULTS

**POSITIVE:** One red line appears in the control line region (C), No apparent red or pink line appears in the test region (T).

**NEGATIVE:** Two red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of HBcAb in whole blood, serum or plasma specimen.  
Neither the quantitative value nor the rate of increase in the concentration of HBcAb can be determined by this qualitative test.
- The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of HBcAb in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
- As with all diagnostic tests, all results must be considered with other clinical information.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B Virus infection.

### PERFORMANCE CHARACTERISTICS

#### Sensitivity and Specificity

The Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) was

compared with leading commercial EIA HBcAb test, the results show that the Hepatitis B Core Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

Method		ELISA		Total Results
HBcAb Test Device	Results	Positive	Negative	
	Positive	443	4	
	Negative	17	120	
Total Results		460	124	584

Relative Sensitivity: 96.3%

Relative Specificity: 96.8%

Accuracy: 96.4%

### REFERENCE

- Chizzali-Bonfadin C., Addlassnig K.P., Kreihsl M., Hatvan A., Horak W., Knowledge-based interpretation of serologic tests for hepatitis on the World Wide Web. Clin Perform Qual Health Care 1997 Apr-Jun 5: 61-3
- ter Bog F., ten Kate F.J., Cuypers H.T., Leentvaar-Kuipers A., Oosting J., Wertheim-van Dillen P.M., Honkoop P, Rasch M.C., de Man R.A., van Hattum J., Chamelueau R.A., Reesink H.W., Jones E.A., Relation between laboratory results and histological hepatitis activity in individuals positive for hepatitis B surface antigen and antibodies to hepatitis B e antigen, Lancet 1998 June 351: 1914-8ng Infect Dis. 1997; 3: 213±221. <https://doi.org/10.3201/eid0302.970219> PMID: 9204307

# TECO

MEDICAL INSTRUMENTS  
PRODUCTION+TRADING GMBH

Dieselstraße 1

D-84088 Neufahrn N.B.

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fax: +49-8773/707 80-29

## TO WHOM IT MAY CONCERN

To any governmental departments,  
registration and/or trade offices in MOLDOVA

### Distribution Authorisation Letter

This letter confirms that

**Sanmedico**  
**Mun. Chisinau**  
**Str. Petricani 88/1 of. 10**  
**Republica MOLDOVA**

is the **legal, exclusive and sole** representative of **TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn NB, Germany**, for the territory of **MOLDOVA** only for all TECO products listed below. **Sanmedico** may participate in public and private tenders, providing sales to all TECO customers in the territory. We as manufacturer certify that our warranty is duly passed to the purchaser through **Sanmedico** for the price, delivery schedules and the specifications of the published literature, catalogues and fully covering the commodities offered.

**Sanmedico** will provide the following information to TECO GmbH when so required in relation to its market surveillance activities:

Reporting of incidents to TECO must take place within 3 working days

Serial number of the device, exact location of the device and the user.

#### Validity:

January 1<sup>st</sup>, 2023 to December 31<sup>st</sup>, 2024

#### Termination:

Confirmation ends automatically on Dec. 31<sup>st</sup> of 2024  
and must be then renewed.

#### Products:

- |                                                                      |                                                           |
|----------------------------------------------------------------------|-----------------------------------------------------------|
| • Coatron M1                                                         | Semi-automated 1-channel Coagulometer (out of production) |
| • Coatron M2                                                         | Semi-automated 2-channel Coagulometer (out of production) |
| • Coatron X Eco                                                      | Semi-automated 1-channel Coagulometer                     |
| • Coatron X Pro                                                      | Semi-automated 2-channel Coagulometer                     |
| • Coatron X Top                                                      | Semi-automated 4-channel Coagulometer                     |
| • Coatron A4                                                         | Fully automated Coagulometer, 4 optic channels            |
| • Coatron A6                                                         | Fully automated Coagulometer, 6 optic channels            |
| • Coatron A6 plus                                                    | Fully automated Coagulometer, 6 optic channels            |
| all instruments with complete accessory, consumables and spare parts |                                                           |
| • Hemostasis Reagents                                                | Complete product line                                     |

This document is signed in Neufahrn, Germany, on January 18<sup>th</sup>, 2023

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl



# Certificate of Approval

This is to certify that the Management System of:

## TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

**ISO 13485:2016**

Approval number(s): ISO 13485 – 00038268

**The scope of this approval is applicable to:**

Design, development, manufacturing, storage and sales of coagulation instruments and in-vitro-diagnostic reagents used in the hemostaseology and coagulation.



**Paul Graaf**

Area Operations Manager, Europe

Issued by: LRQA Limited







# KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Doc#200/08-2022

Hersteller / Manufacturer:

**TECO Medical Instruments  
Production + Trading GmbH**

Adresse / Address:

**Dieselstrasse 1, 84088 Neufahrn, Germany**

Marktakteur / Actor ID SRN:

**DE-MF-000022642** <https://ec.europa.eu>

Wir erklären hier für die im Anhang A ( Seite 2 – 23 IVD Produkte) spezifizierten Produkte dass sie gemäß der Richtlinie für In-vitro-Diagnostika Medizinprodukte 98/79/EC klassifiziert sind als allgemeine IVD.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers i.V.m. Artikel 110 Abs.3 und Abs.4 der Verordnung (EU) 2017/746 und des § 8 Abs.1 des Medizinprodukte-Durchführungsgesetzes, in der jeweils geltenden Fassung, ausgestellt.

Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

We declare herewith for the products specified in Annex A ( page 2 - 23 IVD products) that they are classified as general IVD according to the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of the manufacturer in according to article 110 para.3 and para.4 of Regulation (EU) 217/746 and section 8 para.1 of the Medical Device Law Implementing Act.

In case of unauthorised modifications to the products or un-intended use, this declaration loses its validity.

Sie entsprechen den anwendbaren Anforderungen der Richtlinie:

They meet applicable requirements of:

Richtlinie 98/79/EG über In-vitro-Diagnostika  
klassifiziert gemäß Artikel 9 als "alle anderen Produkte"

Directive 98/79/EC on in-vitro-diagnostic medical devices  
classified according to article 9 as „all other products“

Die Qualitätssicherung entspricht den Anforderungen der  
Richtlinie 98/79/EG über In-vitro-Diagnostika  
für diese Art von Produkten.

The Quality Assurance is in accordance with the requirements  
of Directive 98/79/EC on in-vitro-diagnostic medical devices  
for those kind of products.

Der implementierte QM-Prozess entspricht der EN ISO 13485:2021

The implemented QM Process complies with EN ISO 13485:2021

Die vorstehende Konformitätserklärung ist gültig für alle Chargen  
dieser Produkte, die nach dem Datum der Unterzeichnung in Verkehr  
gebracht wurden.

The above mentioned declaration of conformity is valid for all lots  
of this product, which are distributed after the date of signature.

Das Konformitätsbewertungsverfahren entspricht Anhang III  
der Richtlinie 98/79/EG über In-vitro-Diagnostika  
für diese Art von Produkten.

The conformity assessment procedure complies with Annex III  
of Directive 98/79/EC on in-vitro-diagnostic medical devices  
for those kind of products.

Ort und Datum der Unterzeichnung:  
Place and date of issue:

Neufahrn, 2022-08-31

  
Christian Hötzel  
Verantwortliche Person / PRRC



Doc#200/08-2022

## KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Directive 98/79/EC Annex A

Übrige Produkte – Reagenzien für In-vitro-Diagnostika

Other products – Reagents for in vitro diagnostic – general IVD

Pos.	Article No	Tradename	Unit	Generic Device Term	EMDN / GMDN Code EUDAMED DI
1	A0230-040	TEClot PT-S (Quick)	10x4ml PT-S	Prothrombin time ( quick test )	W0103020101 / 30539 B-PTS-A0230-040X7
2	A0230-100	TEClot PT-S (Quick)	10x10ml PT-S	Prothrombin time ( quick test )	W0103020101 / 30539 B-PTS-A0230-100WY
3	A0260-050	TEClot PT-B (Owren)	5x10ml PT-B	Prothrombin time ( quick test )	W0103020199 / 55986 B-PTB-A0260-050G2
4	A0320-050	TEClot APTT-S	10x5ml APTT-S	Activated partial thromboplastin time	W0103020102 / 55982 B-APTS-A0320-050AM
5	A0401-020	TEClot TT	10x2ml TT	Thrombin time / reptilase / batroxbin time	W0103020103 / 55988 B-TT-A0401-0207P
6	A0511-020	TEClot FIB	10x2ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-020N2
7	A0511-050	TEClot FIB	10x5ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-050NB
8	C1010-020	TEChrom AT	6x6ml reagent FXa 3x3 ml substrate	Antithrombin	W0103020602 / 56156 B-AT-C1010-020HL
9	D2010-012	Red D-Dimer	3x4ml latex 3x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2010-0126W
10	D2020-005	Blue D-Dimer LC	1x5ml latex LC 1x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2020-0057E
11	P8001-010	TECal N	10x1ml	Calibration plasma for haemostasis	W0103020701 / 45786 B-CAL-P8001-005X8
12	P8200-005	TECal DD	5x1ml	Calibration plasma for haemostasis	W0103020701 / 47348 B-CAL-P8200-005XX
13	P6001-010	TEControl N	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6001-010H7
14	P6101-010	TEControl A	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6101-010HQ
15	P6201-010	TEControl A Plus	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6201-010J9
16	P5001-010	TEClot Factor II	10x1ml	Coagulation factor ii ( prothrombin )	W0103020202 / 30542 B-FAC-II-P5001-010ML
17	P5101-010	TEClot Factor V	10x1ml	Coagulation factor v	W0103020204 / 30544 B-FAC-V-P5101-010AN
18	P5201-010	TEClot Factor VII	10x1ml	Coagulation factor vii	W0103020205 / 30545 B-FAC-VII-P5201-0107B
19	P5301-010	TEClot Factor VIII	10x1ml	Coagulation factor viii	W0103020207 / 30547 B-FAC-VIII-P5301-01097
20	P5401-010	TEClot Factor IX	10x1ml	Coagulation factor ix	W0103020208 / 30548 B-FAC-IX-P5401-0106C
21	P5501-010	TEClot Factor X	10x1ml	Coagulation factor x	W0103020209 / 30549 B-FAC-X-P5501-010EQ
22	P5601-010	TEClot Factor XI	10x1ml	Coagulation factor xi	W0103020210 / 30551 B-FAC-XI-P5601-010A8
23	P5701-010	TEClot Factor XII	10x1ml	Coagulation factor xii	W0103020211 / 30552 B-FAC-XII-P5701-010CJ

(Recital 23 of Directive 98/79/EC on In Vitro Diagnostics Medical Devices) - Annex A - general IVD



# KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Doc#001-01/06-2022

Hersteller / Manufacturer:

**TECO Medical Instruments**

Adresse / Address:

**Production and Trading GmbH****Dieselstrasse 1, 84088 Neufahrn, Germany**

Marktakteur / Actor ID SRN:

**DE-MF-000022642** <https://ec.europa.eu>

Die hier benannten Produkte der generischen Produktgruppe erfüllen die Anforderungen der aufgeführten Verordnungen, Richtlinien und Normen. Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

**BASIS UDI-DI 426018278CMX81152**

IVD - halb-automatische Blutgerinnungsmessgeräte - Handelsbezeichnung, Typ, Kat.-Nr.

IVD - semi-automated Coagulation Systems - trade name, type, model, Cat.-No.

**Coatron X Eco / Coatron X Pro / Coatron X Top****81 101 10****81 101 20****81 101 40**

The products of the generic product group named here fulfil the requirements of listed regulations, directives and standards. In the case of unauthorised modifications to the product or use not in accordance with the intended purpose, this declaration becomes invalid.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

**Verordnung (EU) 2017/746**

für in-vitro Diagnostika-IVDR

und dem harmonisierten Standard am 2022-05-12:

Risikoklassifizierung gemäß Artikel 47-Anhang VIII

**Regel 5 b – „Klasse A“**

Konformitätsbewertungsverfahren gemäß:

(EU) 2017/746 Artikel 17 (Anhang II+III)

Angewandte Normen zur Sicherstellung der grundlegenden Anforderungen an Leistung und Sicherheit:

EN ISO 18113-3:2011

DIN EN 62304:2018

DIN EN 62366-1

DIN EN 62366-1:2017

DIN EN 61326-1:2013

DIN EN 55011:2009 + A1:2010

IEC 61010-1:2010, AMD1:2016

IEC 61010-2-101:2015

IEC 61010-1:2010

Richtlinie 2011/65/EU RoHS III

(incl. (EU) 2015/863) - DIN EN IEC 63000

QM-System gemäß (EU) 2017/746 Art.10(8)

angewandter Standard: EN ISO 13485:2021

**Regulation (EU) 2017/746**

for In-vitro diagnostic medical devices

and it's harmonized standard at 2022-05-12:

Risk classified according to article 47 annex VIII

**Rule 5 b – "Class A"**

Conformity assessment procedure in accordance with:

(EU) 2017/746 Article 17 (annex II+III)

Standards applied to ensure the essential requirements for performance and safety:

EN ISO 18113-3:2011

DIN EN 62304:2018

DIN EN 62366-1

DIN EN 62366-1:2017

DIN EN 61326-1:2013

DIN EN 55011:2009 + A1:2010

IEC 61010-1:2010, AMD1:2016

IEC 61010-2-101:2015

IEC 61010-1:2010

Directive 2011/65/EU RoHS III

(incl. (EU) 2015/863 - DIN EN IEC 63000

QM-Systems in accordance with (EU) 2017/746 art.10(8)

Applied standard procedure: EN ISO 13485:2021

Ort und Datum der Unterzeichnung:

Place and date of issue:

Neufahrn, 2022-06-21

Matthias Dieckmann  
General Manager



Christian Hötzel  
Verantwortliche Person / PRRC





Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



# TECO

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# CERTIFICATE

for: **Mr. Vitalie Goreacii**

Company: **Sanmedico SRL**  
Str. Petricani 88/1, oficiul 10  
Chisinau - Rep. Moldova MD-2059  
MOLDOVA

have participated with success at the intensive training session:

**Application and technical training for following instruments:**

- **Coatron X series**
  - **Installation**
  - **Application**
  - **General use, also in combination with TECAM Software**
  - **Technical and After Sales Service**

Supervisors: **Mr. Chr. Hoetzi and Mrs. Wendy Guo**

Place of Training: **TECO – Germany**

Date: **November 18<sup>th</sup>, 2019**



Christian Hoetzi  
General Manager



TOP  
INNOVATION  
2017 - 2018

Clotting  
Chromogenic  
Immunturbidimetric

# Coatron

Semi-automated  
Coagulation Analyzer Series

With 1, 2 or 4 optical channels



# TECO

Innovation in Coagulation

# A new area of manual and semi-automated Coagulation Analyser rise up

The Coatron X instrument line is a consequent continuation in the development of the Coatron product line. Over 25 years in experience and innovation is the reference for our new Coatron X instrumentation line.

The unique detection principle in combination with the high-level analytical algorithm calculates exact, precise and reproducible results.

Easy in operation – self instructing user dialogue - reliable

## **Highest optical resolution, enlarged optic range, smallest sample and reagent volume**

0.1 mOD, 0 - 3800 mOD, just with 75 µL sample and reagent volume

## **Complete optical analysis**

No further parts required, like balls, stirrers etc.

## **Adaptation of the light level**

Automatic light level adjustment of the optic channels to each sample

## **Exclusion of disturbance**

Stray light reduction, exact temperature control, all parameter are preset



“Complete range of Coagulation Analysis with the highest standard and reliability. The new generation of Coagulation instruments with optical detection are here.”

Coatron X - product family



With 1, 2 or 4 optical channels.

[www.teco-medical.com](http://www.teco-medical.com)

## Prepared for the daily routine and the upcoming requirements

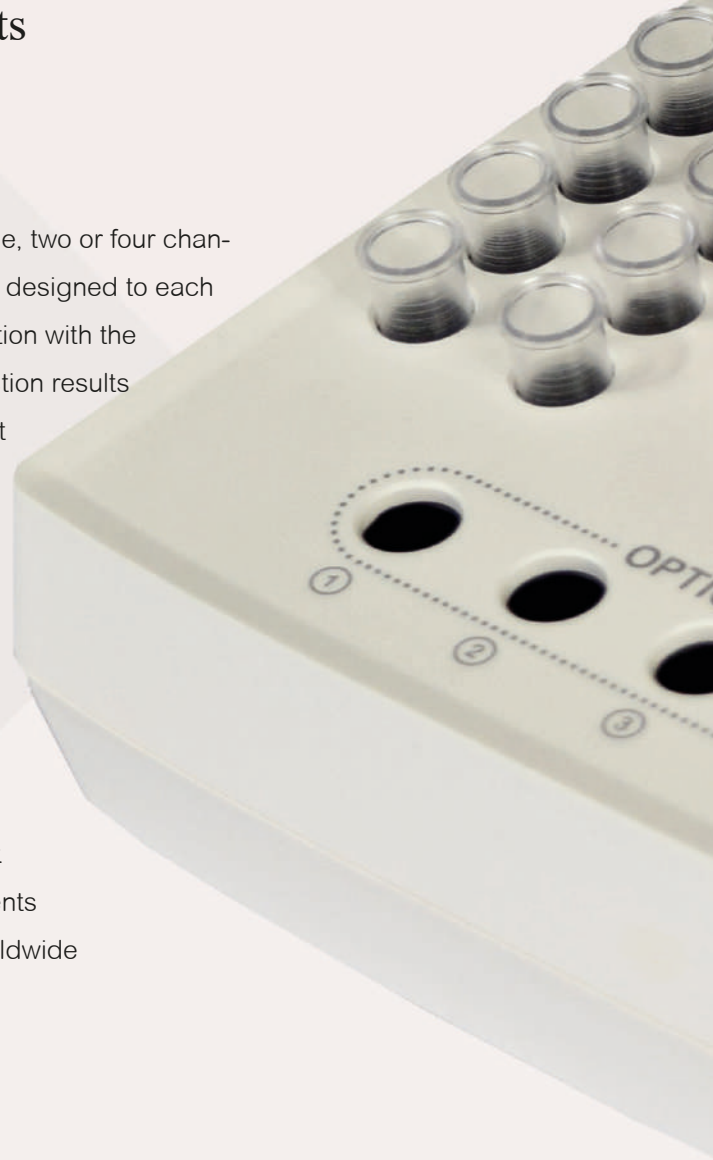
### One instrument – many possibilities

The Coatron X family is prepared to work with one, two or four channels. The built-up and functionality is specifically designed to each instrument version and requirements. The operation with the intuitive user dialogue and handling of the detection results are easy and effective. The possibility to connect the instrument to the **TECO Cloud** offers new perspective of instrument, reagent and consumables verification and handling. The precise and correct patient result is what we want to secure.



### Quality is our basic demand

TECO develop and produce with qualified and specialized companies, located in Germany. High reliability, nearly maintenance free instruments are our benefit. Our reference is 25 years, in worldwide laboratories, with satisfied users.



### TECO Cloud Services – A strong data bank and application service behind

All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.





Coatron	Eco	Pro	Top
General			
Dimensions	230 x 148 x 94 mm (l, b, h)		
Display	Colored touch display 4.3"		
Pre-warm temperature	37°C		
Pre-warm cuvettes (pcs.)	10	20	20
Pre-warm reagent 24mm (pcs.)	1	1	1
Pre-warm reagent 22mm (pcs.)	2	2	2
Pre-warm reagent 11mm (pcs.)	2	2	2
Reagent mixing position	-	1	1
Power values	110-240Vac, 50-60Hz / 5Vdc, 3.3A		
Interfaces			
RS232 (2x)	Printer, Barcode reader		
USB (2x)	Network, Firmware update		
Bluetooth	TECO Cloud, App		
Optic / tests			
Optic channels	1	2	4
Wavelength (nm)	620 (red)	405 (UV)	405 (UV)
Global Coag. tests	PT, APTT, TT, FIB		
Specific Coag. tests	-	individual factors	
Chromogenic Coag. tests	-	AT, PC	
Latex based tests	D-Dimer		
Whole blood tests	PT-B	-	



## The details make the difference

### Coatron X

The remarkable details in every single component is achieved by selecting of premium suppliers.

The performance of a high level instrument is strongly depending on the concept in general and the perfect usability to reach the requirements of a modern laboratory analyser.

Priority No. 1 was to get a daily routine reliability and easy-to-use operation.

### Software and connection possibilities

With the Coatron X product family starts a new time line in analysis management and service maintenance. Operation via intuitive, colored touchscreen, as well patient result management are perfectly optimized.

## Operation details

Coatron	Eco	Pro	Top
<b>Operation</b>			
Touchscreen 4.3"	✓	✓	✓
Real time clock	✓	✓	✓
Stopwatch	✓	✓	✓
Language selection	✓	✓	✓
<b>Interfaces</b>			
USB to LIS	✓	✓	✓
Network to LIS (TECAM software required)	✓	✓	✓
<b>Management</b>			
Test calibration	✓	✓	✓
Tracking to Pat.ID, Patient ID, Sample ID or Auto ID	✓	✓	✓
Automatic optic start (no Starterpipette required)	✓	✓	✓
Double determination	✗	✓	✓
Sample management (ID)	✗	✓	✓
Reagent management (ID) (lot und expiry)	✗	✓	✓
Internal result databank	✗	✓	✓
Patient identification with barcode	optional		





### Intuitive operation and control

Clear and easy to operate user dialogue with a high quality colored touchscreen

- Direct usable
- Short learning phase
- Logic, intuitive operation
- Reliable touchscreen surface
- Quick touch response



### For small and mediate laboratory requirements

Concept is suitable for daily routine work in Coagulation laboratories and hospitals

- Three different versions available, depending on number of samples per day
- In maximum up to 4 optic channels available

### Interfaces

#### RS232 (2x)

- For external serial printer and external barcodereader

#### LIS/USB

#### Bluetooth



Integrated barcode scan for reagents.





### **TECO Cloud Services**

#### **A strong data bank and application service behind**

All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.



For trading partners worldwide, please visit our web-page

#### **TECO Medical Instruments Production + Trading GmbH**

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**TECO**  
Innovation in Coagulation

# TECO

## Manual de operare

### Seria X Coatron

Eco / Pro / Top



IVD



REP

*Doar pentru diagnosticul in-vitro*

Dispozitive și reagenți pentru coagulare și hemostază

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OPM Revizuirea 1

Program V01.00.39

Document No: 26 900 01

**Reprezentant autorizat în Republica Moldova:**

**SANMEDICO SRL**

**mun. Chișinău, str. Petricani 88/1, of.10**

**tel: (022) 623 032; 060 155 788**

**Actualizări**

VERSIUNEA INSTRUCȚIUNII UTILIZATORULUI	VERSIUNEA PROGRAMULUI
1	1.00.39 (prima ediție)

**Drepturi de autor**

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**Mărcile comerciale**

**Coatron** este marcă comercială a TECO GmbH. Alte denumiri de produse utilizate în acest manual al operatorului sunt mărci comerciale ale companiilor respective.

**Producătorul**

Dispozitivul este produs de  
**TECO GmbH**  
**Dieselstrasse. 1**  
**D-84088 Neufahrn, Germania**

Telefon: +49 (0) 8773 70780-0  
 Fax: +49 (0) 8773 70780-29  
 Internet: <http://www.teco-gmbh.com>

**Garanție**

**Coatron X** are o garanție de un an după livrare sau după prima instalare. Garanția acoperă orice defecte de material, funcționalitate sau manoperă (a se vedea, de asemenea, „Termenii și condițiile generale”). Prima instalare trebuie înregistrată în „Registrul de instalare”.

Garanția expiră în caz de defecțiuni cauzate de:

- Accident, neglijență în întreținere și înșelăciune, abuz sau utilizarea necorespunzătoare.
- Folosirea de reactivi, materiale consumabile sau piese de schimb neautorizate.
- Deservirea neautorizată. Orice reparație sau deservire trebuie efectuată de persoane autorizate.

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## 1. INTRODUCERE

Acest dispozitiv a fost fabricat în condiții de maximă eficiență în ceea ce privește siguranța și funcționalitatea sa de inginerie. Pentru a menține această condiție și a asigura o operare fără riscuri, operatorul trebuie să respecte avertismentele și informațiile de siguranță din acest manual de utilizare.



**Folosiți Coatron X numai în conformitate cu instrucțiunile din acest manual de utilizare. În caz contrar, producătorul exclude răspunderea pentru daunele aduse dispozitivului Coatron X, pacienților sau operatorilor.**

### 1.1 SIMBOLURI

Următoarele simboluri standard sunt utilizate în acest manual:

SIMBOL	Semnificația	Explicația
Courier	Informație	Buton pe tastatură
CAPS	Informație	Mesaj pe ecran
	Citare	Indică <u>informație importantă</u> și sfaturi
	Informație	Describe reacția Coatron X la intrarea făcută de operator.
	Atenție	Risc de posibile daune de sănătate sau daune considerabile echipamentului dacă nu se ține cont de avertisment.
	Pericol	Risc potențial pentru personalul care operează cu echipament sau pentru dispozitiv din cauza șocului electric.
	Pericol biologic	Echipamentul poate fi potențial infecțios datorită probelor și reactivilor folosiți.
	Radiație laser	Evitați expunerea directă a ochilor

## 1.2 IMAGINI CU DISPOZITIVUL



*Ecranul principal*

*Ecran tactil color*

*Zona completată este preîncălzită până la 37°C*

*1 x poziția reagentului Ø24mm*

*1 x poziția reagentului Ø22mm*

*1 x poziția reagentului Ø22mm, amestecat*

*2 x pozițiile reagentului Ø13mm*

*20 x pozițiile de incubare ale cuvetelor*

*4 x pozițiile de măsurare a cuvetelor*

*(depinde de versiunea ECO/PRO/TOP)*

*Imaginea 1: Vedere de sus*



5V: Cablul de energie

PC: LIS sau PC

DESERVIRE: Actualizarea programului

IMPRIMANTĂ: Impriantă în serie

CODUL DE BARE: Scanner de mână a codurilor de bare

*Imaginea 2: Vedere din spate*



5V: Cablul de energie

PC: LIS sau PC

DESERVIRE: Actualizarea programului

IMPRIMANTĂ: Impriantă în serie

CODUL DE BARE: Scanner de mână a codurilor de bare

*Imaginea 3 : Vederea laterală cu slotul pentru codul*

de bare




### 1.3 UTILIZAREA PROPUȘĂ



Familia COATRON-X este proiectată pentru a efectua teste coagulometrice, cum ar fi PT, PTT, TT, fibrinogen, teste cu un singur factor, teste cromogene și imunoturbidimetrice (de exemplu, antitrombină, D-dimer etc.) pe plasmă citrată umană. Aparatul trebuie utilizat în scopurile preconizate și în condiții tehnice perfecte, de către personal calificat, în condiții de muncă și operațiuni de întreținere, așa cum este descris în acest document. Este conceput pentru mediu de laborator sau clinic și pentru a fi operat de un utilizator instruit. Nu este destinat uzului casnic.

#### 1.3.1 COMPARAȚIA DISPOZITIVELOR COATRON X

Coatron-X este disponibil în trei versiuni diferite numite Eco, Pro sau Top.

Coatron-X	Eco	Pro	Top
			
Canalele optice	1	2	4
Lungimea de undă optică	620nm	405nm	405nm
Cuvete, volum total	Singular, 75μL	Singular, 75μL	Singular, 75μL
Analize totale de coagulare	PT+aPTT+Fib+TT		
Analize speciale de coagulare	-	Toți factorii	Toți factorii
Analize cromogene	-	AT, PC	AT, PC
Analize avansate latex	D-Dimer		
Testarea sângelui integru	Da (PT INR+%)	Nu	Nu
Ecran	TFT 4.3" , 480x272 , 18bit color, multi-touch		
Parametrii fizici	Forma X 225x150x90mm (LxIxÎ) cu imprimeu tampon		
Blocarea reagenților și optică	Preîncălzit la 37°C		
Preîncălzirea cuvetelor	10x	20x	20x
Preîncălzirea reagenților, 24mm	1x		
Preîncălzirea reagenților, 22mm	2x		
Preîncălzirea reagenților, microtuburi	2x		
Agitator de reagenți	nu	1x	1x
Interfața pentru imprimanta din serie	Da		
Interfață pentru scannerul de coduri de bare portabil	Da		
Modulul scannerului de coduri integrat	opțional		
LIS, USB	Da		

Actualizarea programului, USB	Da
Bluetooth V4.0	Urmează

Funcțiile utilizatorului	Eco	Pro	Top
Utilizare intuitivă prin Touchscreen	Da		
nu este necesară experiență sau pregătire			
Algoritmul de coagulare TECO avansat	Da		
Cel mai bun din experiența de 25 de ani			
Lotul de reagent dublu	Nu	Da	Da
gestionati două loturi diferite pentru fiecare test			
Barcodul de reagenți	Da		
LOT de intrare + Detectare LOT de expirare sau LOT pozitiv			
Calibrarea testului	Da		
LOT, expirare și maximum 5 puncte pentru fiecare test			
Codul de bare a pacientului	Da		
Introduceți ID-ul pacientului prin scannerul de coduri de bare până la 16 caractere			
Baza de date a rezultatelor	Nu	Da	Da
Salvați rezultatele în dispozitiv			
Determinarea dublă	Nu	Da	Da
Rulați pacientul de două ori și afișați valoarea medie			
Funcția cronometru	1x	2x	4x
Cronometrați timpul de incubare			
Identificarea rezultatelor	Da		
Numărul de identificare al pacientului, a mostrei sau autoidentificare			
Ceas în timp real	Da		
Funcția dată și timp			
Modificarea limbii	Da		
EN,ESP, ITA, FR,DE – în continuare ca opțiune			
Începeți testarea la adăugarea reagentului	Da		
Nu este necesară o pipetă de start scumpă			
Vizualizați curba de reacție	Da		
Este necesar programul Tecmoni			
Link către LIS prin USB	Da		
Protocolul programului TECAM SMART			
Link către LIS prin rețea / ASTM	Da		
Este necesar programul TECAM SMART			

### 1.3.2 METODE DE TESTARE

Următoarele teste sunt furnizate pentru a detecta afecțiunile sistemului de coagulare uman, care pot fi sângerare sau tromboză și monitorizarea medicamentelor anti-coagulare precum Heparin sau Marcumar.

Testul	Denumirea	Specimen	Coatron X		
			Eco	Pro	Top
<b>PTB</b>	Timpul de protrombină	Sînge	Da	Nu	Nu
<b>PT</b>	Timpul de protrombină	Plasmă	Da	Da	Da
<b>aPTT</b>	Timpul protrombinic parțial activat	Plasmă	Da	Da	Da
<b>FIB</b>	Fibrinogenul	Plasmă	Da	Da	Da
<b>TT</b>	Timpul trombinei	Plasmă	Da	Da	Da
<b>AT</b>	Antitrombina	Plasmă	Nu	Da	Da
<b>DD</b>	D-Dimer	Plasmă	Da	Da	Da
<b>PC</b>	Proteina C	Plasmă	Nu	Da	Da
<b>Factors</b>	Factorii II, V, VII, VIII, IX, X, XI, XII	Plasmă	Nu	Da	Da

### 1.3.3 COLECTAREA MOSTRELOR

Tipul: Plasmă citrată umană  
 Colectarea: puncția venei, 1:10 citrat de sodiu mixt 3.2% (0.105M)  
 Centrifugarea: 10 min la 1500g  
 Păstrarea: Max 4h după colectare, la temperatura camerei

Bilirubina: < 50mg/dl  
 Hemoglobina: < 2000mg/l  
 Trigliceridele: < 50g/l

#### Specimen destinat pentru PTB (Coatron X Eco)

Tipul: sânge capilar din puncția degetului, sânge integru citrat



**În cazul în care există diferențe față de elementele de siguranță ale reactivului, urmați întotdeauna instrucțiunea din cutie.**



### 1.3.4 PRINCIPIUL DE MĂSURARE

Detectarea coagulării plasmatice se bazează pe principiul fotometric. Nu sunt necesare accesorii mecanice precum bilele de amestecare. Plasma de sânge este turnată într-o cuvă. Se adaugă reactivi speciali, care inițiază coagularea sângelui. Cuvă este expusă prin lumină ultravioletă în timpul procesului de coagulare. Când proba începe să coaguleze, se măsoară o schimbare a absorbției luminii. Timpul de la începerea măsurării până la schimbarea luminii (punct de cotitură) se numește timp de coagulare și se exprimă în secunde [s].

Conversia timpului de coagulare într-o unitate de test specifică este una folosind o interpolare liniară, hiperbolică, semi-logaritmică sau dublu-logaritmică a punctelor de calibrare stocate. Modelul matematic actual este tipărit în „SETUP TEST”. Valorile în afara domeniului de calibrare sunt calculate prin extrapolare și marcate ca " \* ".

Unitate	Informație	Locurile decimale	Valoare maximă
s	secunde	1	-
%	activitate	1	180.0
U	unități	0	999
INR	Raport int.	2	30.00
R	raport	2	30.00
NR	raport polonez	0	180
mg/dl		0	900
g/l		2	10.00
IE/ml	Unități int.	2	10.00
mg/l		2	10.00
μg/ml		3	7.000
ng/ml		0	7500
μg/l		0	7500
IU/mL	Unități int.	2	10.00

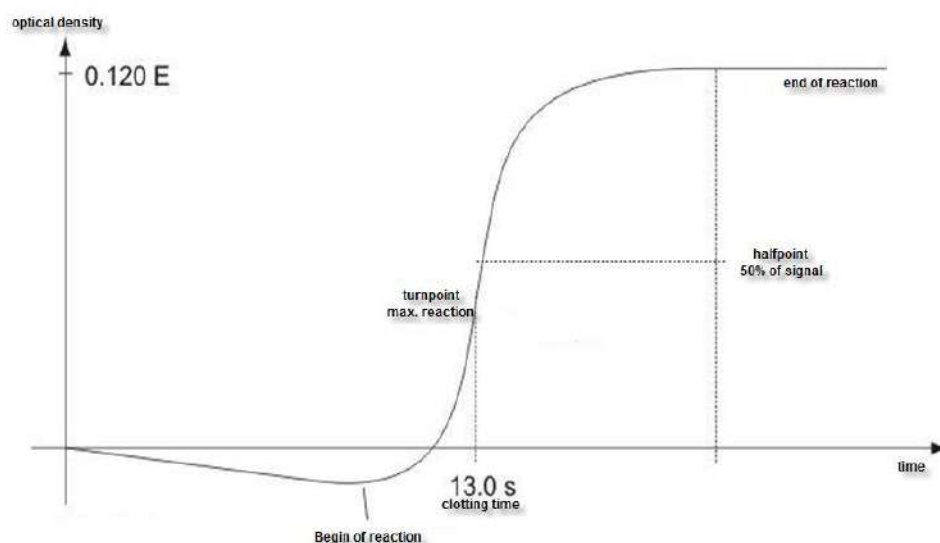
R = timpul de coagulare / timpul normal

NR =  $100 \cdot (\text{timpul normal} / \text{timpul de coagulare})$

INR = Ratio<sup>ISI</sup> (Raport normal internațional)

IU/mL = IE/mL = Unități internaționale (1.00 IU/mL = 100 % activitate)

### 1.3.5 METODA DE COAGULARE (PT, APTT,...)



IMAGINEA 4: DETERMINAREA PUNCTULUI DE ÎNTOARCERE ÎN METODA DE COAGULARE

Reacția finală în cascada de coagulare este transformarea fibrinogenului în fibrină catalizată de trombină. Formarea fibrinei are ca rezultat oglindirea (nivel turbidimetric mai mare) în probă, care este măsurată de fotometru și stocată ca dispariție. Rezultatul în câteva secunde este timpul de la începutul reacției până la momentul vitezei maxime de schimbare (punctul de cotitură al reacției). Dispozitivul poate fi comutat și pentru a defini coagularea la jumătatea punctului de reacție.

### 1.3.6 METODA CROMOGENĂ (ANTITROMBINA):

Schimbarea semnalului optic nu este cauzată de reacția de cheag, ci de eliberarea de particule de culoare (pNA), care provoacă o culoare galbenă. Schimbarea culorii este măsurată la 405 nm și exprimată ca „dE/60sec” și proporțională cu concentrația sau activitatea analitului.

### 1.3.7 METODA IMUNOTURBIDIMETRICĂ (D-DIMER):

Schimbarea luminii este cauzată de reacțiile Antigen - anticorp, care au dispersat lumina. Anticorpul se leagă de particulele de latex la amplitudinea reacției optice. Schimbarea luminii este proporțională cu concentrația de antigen precum D-Dimer și exprimată ca dE/120 sec.

## 1.4 INFORMAȚIA CU PRIVIRE LA SIGURANȚĂ

### 1.4.1 INFORMAȚII DE SIGURANȚĂ PENTRU FUNCȚIONARE



Folosiți numai lichidele de curățare și clătire aprobate de producător. Nerespectarea acestui lucru poate duce la măsurări defectuoase sau defecțiuni ale reactivilor Coatron X. Preveniți scurgerile în analizator. În caz contrar, este necesar ca lucrările de întreținere costisitoare să fie necesare!



Efectuați măsurări de control la intervale regulate pentru a vă asigura că analizorul continuă să funcționeze impecabil .



Dacă dispozitivul este utilizat într-o manieră, care nu este specificată de producător, garanția ar putea fi afectată!



Vă rugăm să citiți manualul de utilizare în întregime înainte de operare. Pentru a asigura un nivel ridicat de performanță și pentru a evita erorile utilizatorului.

### 1.4.2 INFORMAȚII DE SIGURANȚĂ PENTRU MATERIALE



Folosiți numai materiale aprobate și etichetate TECO, cum ar fi cuvete, piese de schimb sau reactivi pentru care dispozitivul este destinat și validat.



Consumabile precum cuvete sau vârfuri galbene sunt destinate obiectelor de unică folosință. Utilizarea repetată poate duce la rezultate false din cauza contaminării. Urmați instrucțiunile din circularele pachetului de reactivi. Utilizarea incorectă poate duce la rezultate false.



Nu folosiți materialele după data de expirare. Reactivii IVD în special expirați pot provoca rezultate false.



Controlați funcția corectă a pipetei manuale în fiecare an pentru a asigura rezultate precise.

### 1.4.3 INFORMAȚII DE SIGURANȚĂ PRIVIND RISCUL PENTRU SĂNĂTATE



#### **Sângerare sau tromboză**

Diagnosticul și medicația sistemului de coagulare uman bazat pe rezultate false poate duce la sângerare critică sau tromboză. Pentru reducerea riscurilor, este esențial să urmăriți indicațiile de mai jos.

Provocată din cauza stării de eroare a dispozitivului, a reactivului sau a datelor de calibrare:

Efectuați un control al calității înainte de a rula o serie de probe de pacient sau după reconstituirea unui flacon sau după calibrarea testului pentru a exclude erorile de date ale dispozitivului, reactivului sau calibrării.

Provocată de o pipetă imprecisă:

Validați pipeta în fiecare an și etichetați ultima dată de validare.

Provocat de alocarea falsă a valorilor țintă

Executați standardele interoperaționale de control al calității.

Provocat de apa purificată

Folosiți doar apă purificată pentru a reconstitui controale sau reactivi. Verificați vizual ca apa să nu conțină impurități.

Provocat de reactivul expirat

Nu folosiți reagentul *in vitro* sau materialele după data lor de expirare.



#### **Material contaminant**

Aveți în vedere toate suprafețele și materialele, care ar putea intra în contact cu plasmă sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.

Evitați contactul

Purtați mănuși de protecție contra infecțiilor medicale pentru toate lucrările, care implică un contact potențial cu materiale infecțioase și utilizați fiecare pereche de mănuși o singură dată. Folosiți un produs dezinfectant pentru mâini, de ex. Sterilium®, pentru a dezinfecta mâinile după finalizarea lucrărilor.

Aruncați

Materialele infecțioase, cum ar fi deșeurile de cuvă și deșeurile lichide, în conformitate cu legile locale, care reglementează materialele infecțioase.

Condițiile de igienă

Validează sistemul de management igienic în conformitate cu biroul federal german GLP pentru bune practici de laborator sau standarde de calitate similare. Orice deșeuri trebuie considerate potențial infecțioase. Trebuie evitat contactul direct. Sunt necesare mănuși de protecție în timpul funcționării, servirii sau curățării.

**Radiație cu lumină LED**

Evitați expunerea directă a ochilor.

Scannerul intern de coduri de bare CCD este atribuit

EN 55022:2010 clasa B, EN 62471:2008

#### 1.4.4 INFORMAȚII DE SIGURANȚĂ PENTRU CURĂȚARE, ÎNTREȚINERE ȘI DESERVIRE

**Despre deservirea autorizată!**

Efectuați numai măsurile de întreținere, reparație și înlocuire enumerate în acest manual de utilizare. O manipulare necorespunzătoare a dispozitivului va anula obligațiile de răspundere ale producătorului și poate face necesară efectuarea apelurilor de servicii, a căror plată nu este acoperită de garanție. Numai Serviciul Clienți autorizat poate efectua reparațiile. Se pot folosi numai piese de schimb originale. Înainte de a efectua orice reparație pe dispozitiv, este foarte important să dezinfectați complet toate piesele posibil contaminate.

**Despre curățire și decontaminare!**

Înainte ca dispozitivul să fie scos din laborator pentru eliminare sau întreținere, acesta trebuie decontaminat. Procedura este descrisă în capitolul „Curățare și întreținere” și trebuie efectuată doar de personal autorizat bine instruit, respectând toate măsurile de siguranță necesare.

**Certificatul de decontaminare este necesar!**

Dispozitivele, care trebuie returnate trebuie să fie însoțite de un certificat de decontaminare completat de responsabilul de laborator. Dacă nu este furnizat un certificat de decontaminare, laboratorul de returnare va fi responsabil pentru taxele rezultate din neacceptarea dispozitivului de către centrul de deservire.






Aveți în vedere toate suprafețele și materialele care ar putea fi în contact cu plasmă sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.



Evitați orice contact direct cu decontaminanți sau dezinfectanți.

### 1.4.5 SIGURANȚA ELECTRICĂ

	<p><b>Precauții:</b></p> <ul style="list-style-type: none"> <li>▪ Evitați lichidele vărsate în sistem. Dar în cazul în care acest lucru se întâmplă, deconectați dispozitivul de la sursa de energie și curățați și uscați toate părțile contaminate.</li> <li>▪ Scoateți cablul de alimentare înainte de a deschide dispozitivul.</li> <li>▪ Nu atingeți piesele electronice în timpul funcționării.</li> <li>▪ Nu folosiți sistemul fără o conexiune adecvată la împământare.</li> <li>▪ Nu întrerupeți niciodată intenționat contactele de protecție la sol.</li> <li>▪ Nu îndepărtați niciodată elementele carcasei, capacele de protecție sau elementele structurale securizate, deoarece acest lucru ar putea expune piese, care transportă curent electric.</li> <li>▪ Asigurați-vă că suprafețele precum podeaua și masa de lucru nu sunt umede în timp ce se lucrează pe dispozitiv.</li> <li>▪ Verificați regulamentul echipamentelor electrice. Conducele sau soclurile defecte trebuie înlocuite fără întârziere.</li> </ul>
	<p><b>Conectați la energie:</b></p> <ul style="list-style-type: none"> <li>▪ Dispozitivul este clasificat în clasa 1 (IEC) și, prin urmare, trebuie să fie legat în mod fiabil și instalat profesional, în conformitate cu reglementările în vigoare privind cablurile electrice și cu standardele de siguranță prevăzute aici.</li> <li>▪ Asigurați-vă că setarea tensiunii de funcționare este corectă înainte de a conecta dispozitivul la rețeaua de alimentare. Citiți capitolul „Instalare” despre condițiile electrice.</li> </ul>
	<p><b>Deconectați de la energie:</b></p> <ul style="list-style-type: none"> <li>▪ Deconectați cablul de alimentare de la priza de perete sau de la sursa de alimentare a dispozitivului.</li> </ul>



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#### 1.4.6 DECLARAȚIA EMC

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Coatron X respectă cerințele privind emisiile și protecția, în conformitate cu GB/T 18268.1 (IEC 61326-1: 2012) și GB/T 18268.26 (IEC61326-2-6: 2012).



Coatron X a fost proiectat, testat și găsit în conformitate cu dispozitivul Clasa A, în conformitate cu GB 4824 (IEC 61000-4). În mediul intern, acest dispozitiv poate provoca interferențe radio, caz în care utilizatorul este obligat să ia măsuri adecvate.



Detectarea mediului electromagnetic este recomandată înainte de a utiliza acest dispozitiv.



Evitați să acționați acest dispozitiv în apropierea unei surse de radiație puternică (de exemplu, o sursă RF ne-ecranată), care poate interfera cu funcționarea corectă a dispozitivului.



Lungimea maximă a cablurilor către dispozitivele externe precum imprimanta, codul de bare sau LIS trebuie să fie mai mică de 3 m pentru a păstra conformitatea cu EMC. (IEC 61326-1:2012)



Nu instalați pe masa metalică de 3m.

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#### 1.4.7 RECICLAREA DISPOZITIVULUI

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Sistemul trebuie decontaminat de deșeurile electrice înainte de transportare către un dispozitiv autorizat.



Dispozitivul trebuie reciclat, așa cum este indicat de DEEE (2002/96/EG).

## 2. INSTALAREA DISPOZITIVULUI **COATRON X**

### 2.1 OBIECTUL LIVRĂRII

Pachet de livrare standard

- 1 buc. **Coatron X**
- 1 buc. Sursa de energie
- 25 buc. Cuvete de unică folosință
- 5 buc. Tuburi pentru reagenți
- 1 buc Manualul utilizatorului



*Imaginea 5: Setul standard la livrare*

Opțional sunt disponibile:

- Imprimantă termică
- Cablul imprimantei
- Rulouri de hîrtie pentru imprimantă (5/ea)
- Pipetă cu volum variabil 10 -100 µl, simplă
- Programul TECAM Smart

## 2.2 CONDIȚII DE LUCRU

### Condițiile de mediu:

Temperatura de operare	15 - 30 °C
Umiditatea	< 70%
Ridicarea deasupra nivelului mării	< 3.000m
Protecție de praf	Gradul 2
Rezistența la impact	În conformitate cu IEC/EN 61010-1, 8.2.2
Nu este permis	Vibrații, lumină directă a soarelui; expunerea directă la condițiile de aer.

### Condițiile electrice:

100-240 VAC, 47 - 63Hz, Clasa-1 (61010)

### Condițiile de păstrare:

0°C to +40°C, maxim 12 luni în ambalajul original

### Condițiile de transportare:

0°C - +40°C, < 70% umiditate relativă

Nu este definit special. Regulamentul general pentru transport poate fi utilizat.

### Condițiile de igienă:

Validat conform sistemului de management igienic în conformitate cu biroul federal german GLP pentru bune practici de laborator sau standarde de calitate similare. Orice deșeuri trebuie considerate potențial infecțioase. Trebuie evitat contactul direct. Sunt necesare mănuși de protecție în timpul funcționării, deservirii sau curățării.

## 2.3 DESPACHETAREA DISPOZITIVULUI COATRON X

Verificați ambalajul Coatron X și al accesoriilor pentru eventuale deteriorări vizibile. Dacă ambalajul este deteriorat, contactați compania de transport pentru a putea fi evaluată orice deteriorare a dispozitivului sau a accesoriilor.

Procedurile la prima instalare:

1. Despachetați și așezați dispozitivul în conformitate cu condițiile de funcționare (a se vedea cu un capitol înainte).
2. Conectați la sursa de energie.
3. Porniți și așteptați până la regimul verde.
4. Atingeți Green Status și selectați „print”.
5. Atașați raportul de sistem în „Înregistrare protocol de instalare” sau casetă.
6. Confirmați funcția corectă a sistemului printr-o măsurare de control al calității cu PT și plasmă de control.

Instalarea programului TECAM Smart

1. Deconectați dispozitivul de la calculator.
2. Rulați TECAM setup.exe.
3. Confirmați, atunci când vi se cere să instalați driver-ul Coatron X.
4. Conectați dispozitivul la calculator. PC-ul ar trebui să mesajeze, că a fost găsit un dispozitiv nou.
5. Reporniți TECAM.

Informații suplimentare pot fi citite în capitolul „7” sau ajutorul online TECAM.



*Păstrați materialul de ambalare original pentru transportul ulterior.*

## 2.4 PORNIREA ȘI OPRIREA

### Pornirea

Conectați la sursa de energie.

Dispozitivul necesită aproximativ 15 min pentru încălzirea blocului optic la 37 ° C. După aceea este gata pentru măsurare, care este indicat cu un LED verde pe afișaj.

### Oprire

Aparatul nu acceptă întrerupător de alimentare. Trebuie să se deconecteze de la energie.

### Regim de așteptare

Comutarea sistemului în standby după 2 min de funcționare inactivă. În standby, luminozitatea afișajului este redusă pentru a economisi durata de viață a afișajului și pentru a reduce consumul de energie.

### Regimul "somn"

Deschideți meniul și atingeți butonul „Sleep”.

Meniul este afișat în partea de sus a ecranului și este disponibil numai dacă nu există nici măsurare. Consumul de energie în timpul somnului este de 0,2W.

### "Trezirea"

Ecranul tactil.



*Nu există niciun risc de deteriorare a sistemului sau de pierdere de date. Sistemul poate fi (de) conectat în orice situații de operare.*

## 2.5 ÎNREGISTRAREA

Producătorul trebuie informat despre data primei instalări. Pentru aceasta, navigați pe site-ul web TECO GmbH [www.teco-gmbh.com](http://www.teco-gmbh.com) și conectați-vă cu datele contului dispozitivului, care sunt afișate în timpul pornirii sau a ecranului cu informații despre sistem sau pe placa de dispozitive.

User= S/N Numărul de serie, de exemplu 0104000005

Pass= PIN Numărul de identificare al produsului, de exemplu 1234 5678 90

## 2.6 GARANȚIA

Termenul de garanție va începe din data livrării sau înregistrării (prima instalare).

### 3. OPERAREA CU DISPOZITIVUL COATRON X

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Coatron X este controlat în totalitate prin ecran tactil.

- Atingere scurtă: Funcția este executată la atingere
- Atingerea lungă: Funcția este repetată de 10 ori
- Textul butonului gri: Funcția este oprită

În timpul măsurării active, unele funcții din meniu nu sunt vizibile sau afișate cu text gri. Oprii măsurarea pe toate canalele pentru a reactiva butoanele.

#### 3.1 GHIDUL RAPID

---

##### Cum se execută o măsurare PT:

1. Porniți dispozitivul și așteptați starea verde (~ 15min până la 37 ° C).
2. Puneți flaconul PT în blocul de reactiv și lăsați să se incubeze timp de cel puțin 5 min.
3. Schimbați testul canalului 1 în „PT”.
4. Plasați cuva în optică.
5. Introduceți 25 ul de probă în cuvă.
6. Apăsați pe „00:00” și așteptați 30 sec.
7. Apăsați „OPTIC-1” și introduceți un PID sau scanați un cod de bare de probă.
8. Adăugați 50 uL reactiv PT, când „Activ” clipește. Măsurarea va fi începută.
9. Așteptați să se rupă rezultatul sau atingeți butonul optic.

##### Activarea multiplă (cu excepția Coatron ECO)

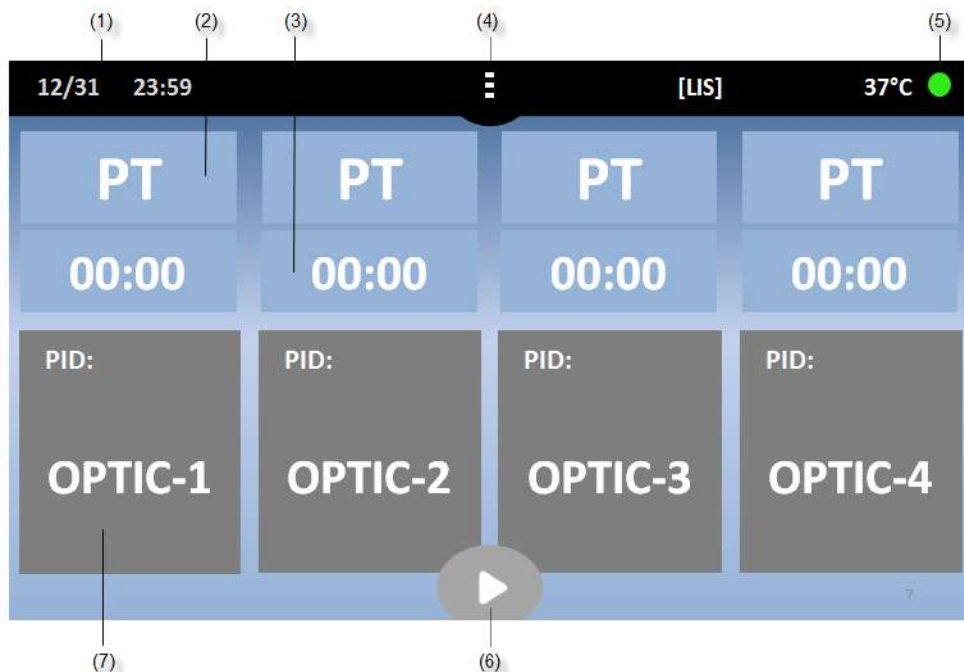
1. Deschideți meniul și setați Auto PID = Pornit.
2. Puneți cuve goale în fiecare canal și pipetați 25 ul de probă pe fiecare cuvă.
3. Apăsați butonul mutlistart.
4. Adăugați 50 ui PT la fiecare cuvă.

##### Cum se introduce o calibrare PT:

1. Porniți dispozitivul și treceți la ecranul de pornire.
2. Atingeți orice buton de testare.
3. Schimbați testul în „PT” și atingeți „Configurare” sau scanați codul de bare al flaconului PT.
4. Introduceți LOT, data de expirare și selectați Unități în „% + INR”.
5. Apăsați din nou butonul „Configurare”.
6. Selectați câmpul de date și schimbați cu butoanele incrementale (- / +). Utilizați funcția de atingere lungă pentru o introducere ușoară.
7. Confirmați cu „OK”.

## 3.2 MĂSURAREA

Primul ecran după pornire



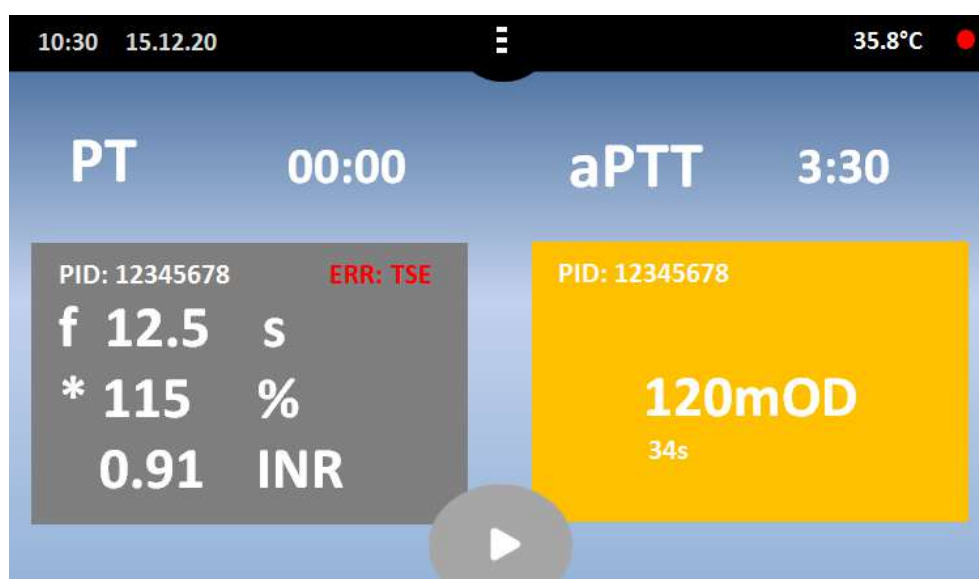
IMAGINEA 6: ECRANUL DE BAZĂ COATRON X TOP

Butonul	Titlul	Utilizarea funcției
(1)	Data și timpul	Redactarea datei
(2)	Testarea	
(2)	curentă	Modificarea testului
(3)	Taimer	Start/Resetarea taimerului sau alarmei
(3)	Meniu sau	
(4)	Acasă	Deschideți meniul sau reveniți la principal
(5)	Verde sau Roșu	Deschideți informațiile despre sistem
(6)	Multistart	Activați toate canalele
(7)	Optic-1	Channel-1 este inactiv. Atingeți pentru a introduce un nou PID și activați
(7)	Activ	Canalul este activ. Atingeți sau adăugați reactiv pentru a începe
(7)	Portocaliu	
(7)	intermitent	Măsurarea continuă. Atingeți pentru a opri măsurarea
(7)	Rezultatul	
(7)	curent	Atingeți pentru a introduce un nou PID



## Altele

eșantion cod de bare	Citiți ID-ul pacientului și urmăriți activarea gratuită
[LIS]	Vizibil, dacă este conectat cu LIS
LED Verde	Sistemul este gata pentru măsurare
LED Roșu	Indică problemele sistemului. Nu este posibilă nicio măsurare.
37.0°C	Temperatura pe blocul de reactiv.
Butoane gri Contrast	Funcția de utilizare nu este posibilă în timpul măsurării.
Întunecat	Modul de salvare. Atingeți pentru a reactiva.



IMAGINEA 7: ECRANUL ÎN TIMPUL MĂSURĂRII

## Butonul (7) în timpul măsurării

PID	Numărul de identificare al pacientului (maxim 16 cifre)
Rezultat	PT = 12.5s, 115% 0,91 INR +++ nici o reacție de cheag nu a fost detectată în timp de execuție
Indicator	f = fibrinogen foarte scăzut (cheag slab) F = fibrinogen foarte mare (cheag puternic) * = Rezultatul nu corespunde cu calibrarea X = valoarea dublă deviază mai mult decât 15%
Err	T = temperatura nu este la 36 - 38°C E = reagent expirat S = intensitatea luminii este prea joasă
mOD	absorbție optică curentă. O schimbare a valoare > 50mOD indică o reacție de cheag în curs.
Taimer	Ora curentă de măsurare

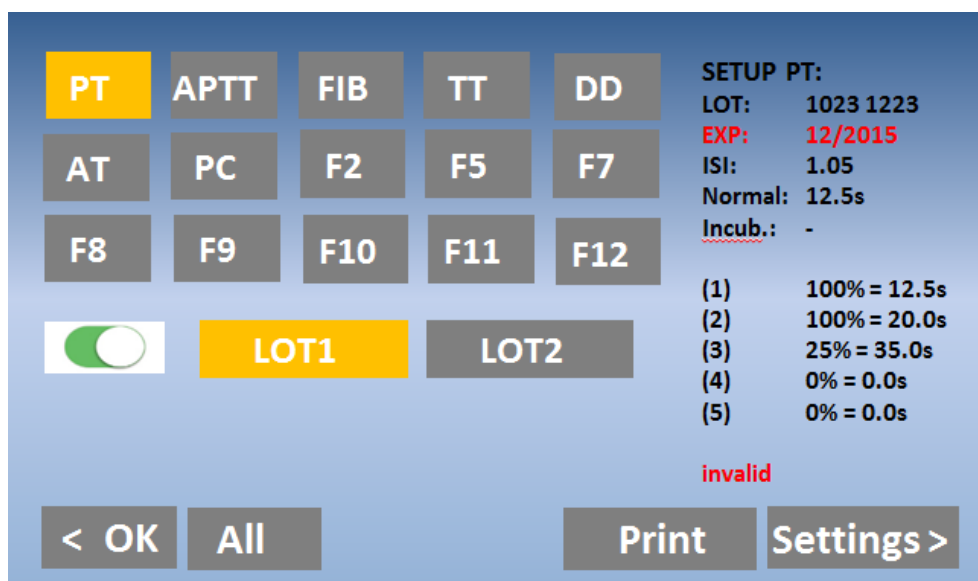
### 3.3 INTRODUCEREA INFORMAȚIEI DESPRE PACIENT

The screenshot displays the patient identification interface. At the top, the label 'PID:' is followed by a text input field containing '1234' and a small 'X' button for clearing the field. Below the input field, there are two buttons labeled '-1' and '+1' for incrementing or decrementing the value. To the right of these is a numeric keypad with buttons for digits 1 through 9, 0, and a 'C' button for clearing. Below the numeric keypad is a 'Hi-Sense' toggle switch, which is currently turned on (indicated by a green circle). At the bottom left, there are two buttons labeled '< OK' and 'ESC'.

IMAGINEA 8: INTRODUCEREA NUMĂRULUI DE IDENTIFICARE AL PACIENTULUI

Buton	Titlu	Funcția utilizată
Taste numerice	0-9, C, X	Modificați sau ștergeți NIP
Incrementa	-1 / +1	Măriți NIP. Utilizați posibilitatea de atingere lungă pentru modificarea ușoară.
Hi-Sense	Hi-Sense	Pornește sensibilitatea foarte înaltă de detecție. Util pentru mostre sau rezultate "+++".
Apăsarea lungă	-	Apăsați butonul > 2 sec
Codul de bare mostră	-	Setați numărul de identificare la codul de bare

### 3.4 ALEGEREA TESTULUI



IMAGINEA 9: ALEGEREA TESTULUI LA COATRON X PRO/TOP

Butonul	Titlul	Utilizarea funcției
<b>Butoanele de testare</b>	PT – F12	Alegeți testul
<b>On / Off</b>	On / Off	Activați două LOT-uri pe test (nu sunt disponibile) pentru Coatron X Eco)
<b>LOT 1/2</b>	LOT 1/2	Încărcați datele LOT 1 sau 2 de la EEPROM
<b>OK</b>	OK	Confirmați testul pentru canalul curent
<b>Toate</b>	Toate	Confirmați testul pentru toate canalele
<b>Setările</b>	Setările	Schimbați calibrarea testului
<b>Print</b>	Print	Tipăriți setarea testului curent

Codul de bare al reagentului

-

Selectați testul curent și lotul.  
Un semnal sonor lung indică codul de bare sau LOT-ul nevalide.

SETAREA PT

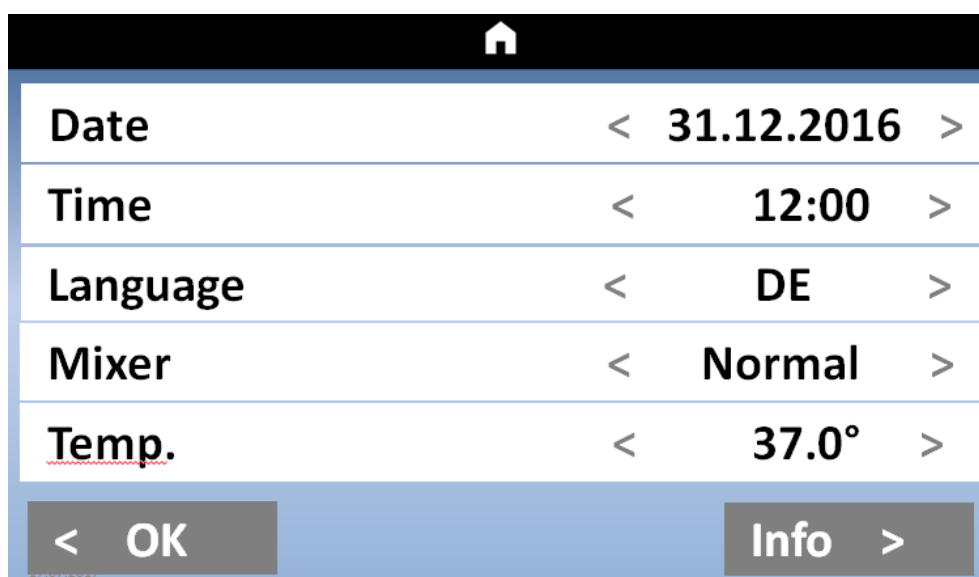
-

Date de calibrare a lotului și testului curent.  
Valorile roșii indică date nevalide.

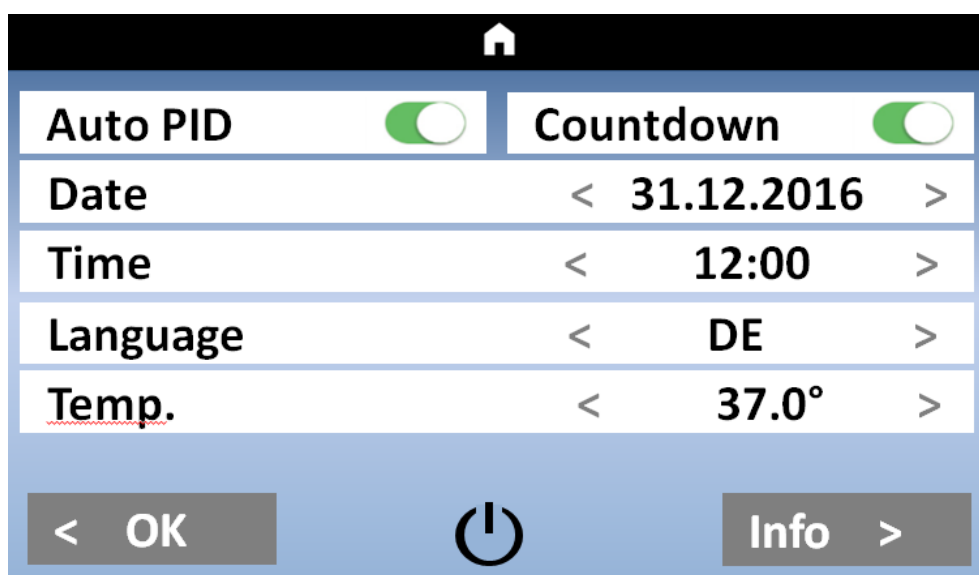
### 3.5 SETĂRILE DE SISTEM



IMAGINEA 10: MENIUL RAPID COATRON X PRO/TOP

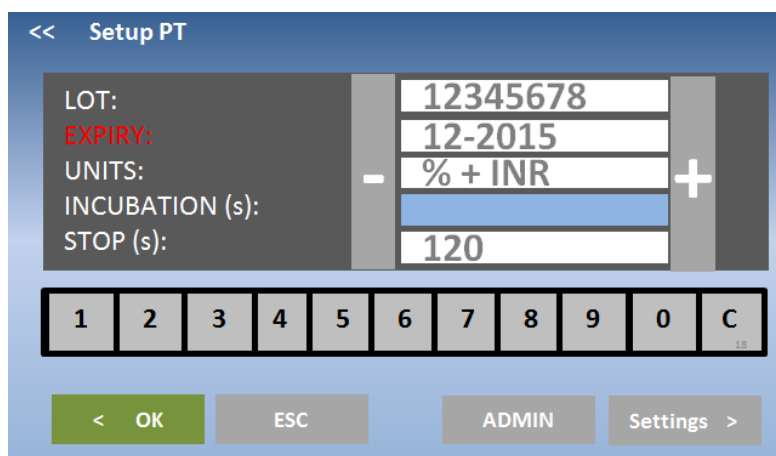


IMAGINEA 11: SETĂRILE DE SISTEM COATRON X PRO/TOP

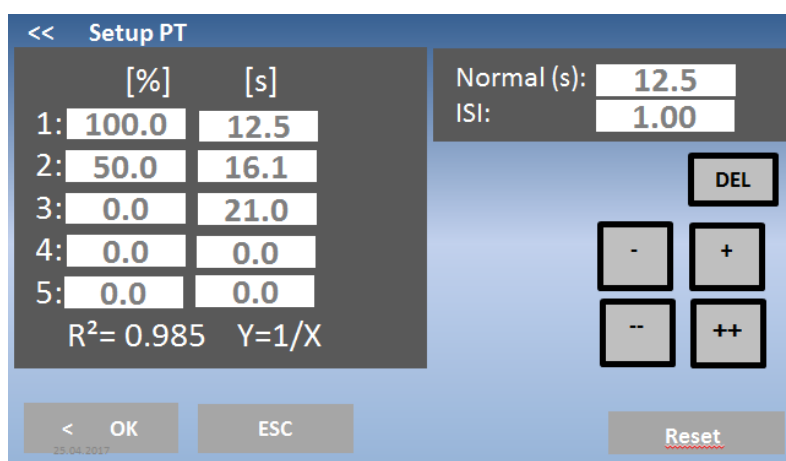


IMAGINEA 12: SETĂRILE DE SISTEM COATRON X ECO

### 3.6 SETĂRILE TESTULUI



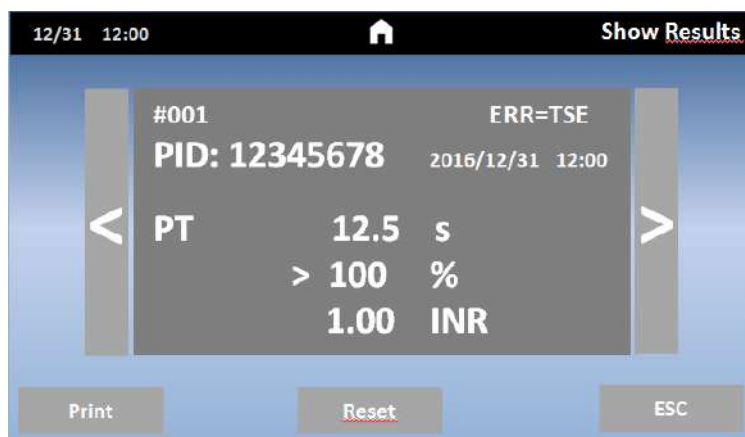
IMAGINEA 13: SETĂRILE TESTULUI 1



IMAGINEA 2: SETĂRILE TESTULUI 2

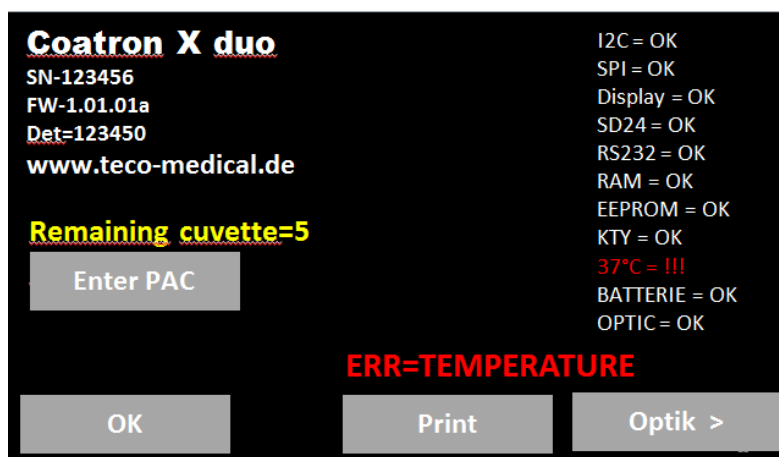


### 3.7 ANALIZAREA REZULTATELOR



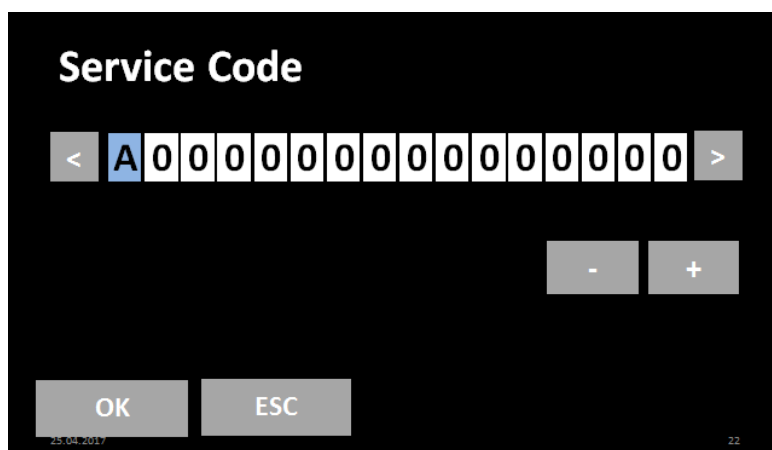
IMAGINEA 15: ANALIZAREA REZULTATELOR COATRON X PRO/TOP

### 3.8 INFORMAȚIA CU PRIVIRE LA SISTEM



IMAGINEA 16: INFORMAȚIA DESPRE SISTEM

### 3.9 INFORMAȚIA PRIVIND INTRODUCEREA TICHETELOR



IMAGINEA 17: INFORMAȚIA PRIVIND INTRODUCEREA TICHETULUI

## 4. TESTE DE COAGULARE DE BAZĂ

### 4.1 DETERMINAREA PT DIN PLASMĂ

#### Cum se execută o măsurare PT:

1. Porniți dispozitivul și așteptați aprinderea stării verzi (~ 15 min până la 37 ° C).
2. Reconstituiți reactivul PT și așteptați 30-60 min înainte de pasul următor.
3. Introduceți flaconul PT în blocul de reactiv + bara de agitare și lăsați să incubeze timp de cel puțin 5 min.
4. Schimbați testul canalului 1 în „PT” apăsând pe testul curent.
5. Puneți cuva goală în optică.
6. Introduceți 25 ul de probă în cuvă.
7. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
8. Apăsați „OPTIC-1” și introduceți un numărul de identificare al pacientului sau scanați un cod de bare de probă.
9. Adăugați 50 uL reactiv PT, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
10. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

#### Activarea multiplă (cu excepția dispozitivului Coatron ECO)

1. Deschideți meniul și setați Auto NIP = Pornit.
2. Puneți cuve goale în fiecare canal și pipetați 25 ul de probă pe fiecare cuvă.
3. Apăsați butonul multistart.
4. Adăugați 50 ul PT în fiecare cuvă de la stânga la dreapta.

#### Cum se calibrează:

1. Reconstituiți calibratorul și așteptați 15-30 min înainte de a continua cu pasul următor
2. Calibratoare.  
Valoarea țintă a calibratorului este starea la certificat. Îmi asum 100% ca exemplu  
Soluția IBS, Owrens sau NaCl2 pot fi utilizate ca diluant pentru probă
  - a. 100%: Pipetați calibrul 100 µl în tubul gol
  - b. 50%: Pipetați 100 uL 100% calibrator + 100 ul diluant în tubul gol
  - c. 25%: Pipetați 100 uL 50% calibrator + 100 ul diluant în tubul gol
  - d. 12,5%: Pipetați 100 uL 25% calibrator + 100 ul diluant în tubul gol
3. Rulați toate cele 4 calibrate ca pacienții și notați timpul de coagulare  
(se recomandă efectuarea determinării duble)
4. Introduceți setările PT și introduceți
  - a. LOT corect, Exp (citiți codul de bare al etichetei flaconului)
  - b. setați UNITATE la „INR + %”
  - c. Timp normal de intrare (= 100% rezultat) + ISI (a se vedea flaconul)
  - d. % Calibrare de intrare

## 4.2 DETERMINAREA PT DIN SÎNGE CAPILAR

### Cum se execută o măsurare PT-B din sângele capilar:

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 ° C).
2. Schimbați testul în „PTB” apăsând pe testul curent.
3. Reconstituiți PT-B cu componenta-1 (diluant) și așteptați 30-60 min înainte de pasul următor.
4. Adăugați componenta-2 (CaCl<sub>2</sub>) în PT-B și așteptați din nou timp de 30-60 min înainte de pasul următor.
5. Puneți cuva goală în optică sau în pre-incubare.
6. Introduceți 150 ul de PT-B în cuvă. Cuvă trebuie folosită în următorii 10 minute.
7. Închideți flaconul PT-B și păstrați-l în frigider până la următoarea utilizare. Reactivul este stabil timp de 30 de zile.
8. Apăsăți „OPTIC-1” și introduceți un NIP (număr de identificare al pacientului) sau scanați un cod de bare de probă.
9. Când „activ” clipește, străpungeți degetul și pipetați 15μL de sânge capilar în cuvă.
10. Măsurarea ar trebui să înceapă. Este important să amestecați în cuvă. Pentru aceasta coborâți pipeta în cuvă și pompați 10-15x în sus și în jos. Terminați amestecarea celei mai recente probe atunci când numărătoarea inversă ajunge la zero.

### Cum se calibrează PTB

1. Reconstituie calibratorul cu 1,7mL și așteaptă 15-30min
2. Calibratoare.  
Valoarea țintă a calibratorului este starea la certificat. Îmi asum 100% ca exemplu  
Soluția IBS, Owrens sau NaCl<sub>2</sub> pot fi utilizate ca diluant pentru probă
  - a. 100%: Pipetați calibrul 100 μl în tubul gol
  - b. 25%: pipetați 100ul 100% calibrator + diluant 500 ul în tubul gol
3. Rulați toate cele 4 calibrate ca pacienții și notați timpul de coagulare
4. Introduceți setările PTB și introduceți
  - a. LOT corect, Exp (citiți codul de bare al etichetei flaconului)
  - b. setați UNITATE la „INR + %”
  - c. Timp normal de intrare (= 100% rezultat) + ISI (a se vedea flaconul)
  - d. % Calibrare de intrare

## 4.3 DETERMINAREA APTT

### Cum să executați o măsurare aPTT:

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 ° C).
2. Schimbați testul în „APTT” apăsând pe testul curent.
3. Puneți CaCl în dispozitiv, lăsați să se incubeze timp de cel puțin 5 min.
4. Puneți cuva goală în optică sau în pre-incubare.
5. Introduceți 25 ul de probă în cuvă.
6. Introduceți 25 uL de reactiv aPTT rece în cuvă.
7. Apăsăți „00:00” pentru a porni cronometrul și așteptați 180 de secunde.
8. Cu puțin înainte de sfârșitul incubării, apăsăți „OPTIC-1” și introduceți un NIP sau scanați un cod de bare.
9. Adăugați 25 ul de CaCl, când „Active” clipește. Măsurarea va începe automat.
10. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

## 4.4 DETERMINAREA FIB

### Cum să executați o măsurare FIB:

#### Metoda nr.1

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 °C).
2. Schimbați testul în „FIB” apăsând pe testul curent.
3. Reconstituiți reactivul FIB și așteptați 30-60 min înainte de pasul următor.
4. Puneți flaconul FIB nu în blocul de reactiv. Temperatura camerei este potrivită.
5. Puneți cuva goală în optică.
6. Introduceți 10 uL de probă în cuvă.
7. Introduceți 90 uL de tampon IBS în cuvă.
8. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
9. Apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare de probă.
10. Adăugați 50 µL de reactiv FIB, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
11. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

#### Metoda nr.2

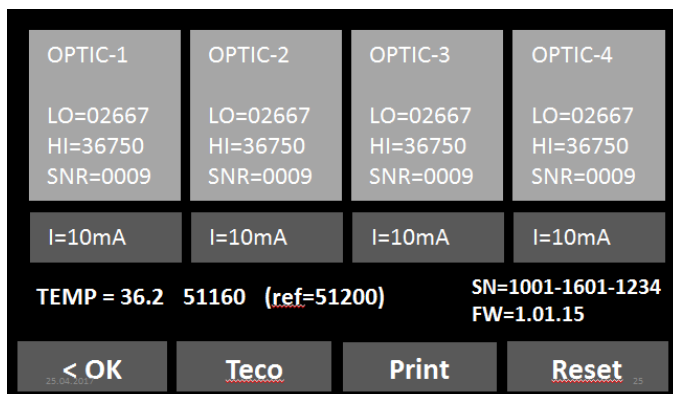
1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 °C).
2. Schimbați testul în „FIB” apăsând pe testul curent.
3. Reconstituiți reactivul FIB și așteptați 30-60 min înainte de pasul următor.
4. Puneți flaconul FIB nu în blocul de reactiv. Temperatura camerei este potrivită.
5. Pipetați 50 uL de probă prediluată 1: 10 în cuvă (prediluarea se face cu sol. IBS).
6. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
7. Apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare de probă.
8. Adăugați 25 µL de reactiv FIB, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
9. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

### Cum să calibrezi FIB

1. Reconstituiți calibratorul și așteaptă 15-30min înainte de a continua cu pasul următor
2. Calibratoare.  
Valoarea țintă a calibrаторului este starea la certificat. Se presupune ca exemplu 300mg / dL
  - a. 600 mg / dL: Pipetați 50 pi calibrator + 200 uL tampon IBS în tubul gol
  - b. 300 mg / dL: Pipetați 50 pi calibrator + 4500 pL tampon IBS în tubul gol
  - c. 150 mg / dL: Pipetați 50 pi calibrator + 950 uL tampon IBS în tubul gol
  - d. 75 mg / dL: Pipetați 50 pi calibrator + 1950 uL tampon IBS în tubul gol
3. Rulați totți 4 calibratori
  - a. Adăugați 50 uL de calibrator în cuvă
  - b. Adăugați 25 uL de reactiv FIB pentru a începe măsurarea. Scrieți timpii de coagulare pe hârtie sau imprimați
4. Introduceți setările FIB și introduceți
  - a. LOT corect, Exp
  - b. setați unitățile la “mg/dL”
  - c. Introduceți calibrarea mg/dl

## 5. FUNCȚIILE DE DESERVIRE

### 5.1 VERIFICAREA OPTICĂ



IMAGINEA 18: VERIFICAREA OPTICĂ

### 5.2 RAPORTUL DE SISTEM

SYSTEM REPORT

22.08.2017

System:

Coatron X

Version:

V1.01.42

SIN :

01040 01234

PIN:

12345 67890

TEMP:

37.0°C

50981 (target=50992)

Optic:

Lo	Hi	mA	Qc	
1:2698	28822	5	6	OK
2:2698	29822	6	3	OK
3:2698	30822	7	1	OK
4:2698	29822	6	0	OK

PT=

26

aPTT=

8

FIB=

17

DD=

0

AT=

0

TOTAL

101

*Data raportului*  
*denumirea sistemului*  
*versiunea programului*  
*numărul de identificare al sistemului*  
*numărul de identificare al produsului*  
*temperatura opticii și valoarea digitală al senzorului*  
*temperaturii*  
*Valorile optice*  
*Lo= LED stins*  
*Hi= LED pornit*  
*mA= energia LED*  
*Qc= zgomotul opticii*  
*OK= nu există eroare*  
*!= condiție de eroare*

*Numărarea testelor efectuate*



### 5.3 AJUSTAREA TEMPERATURII

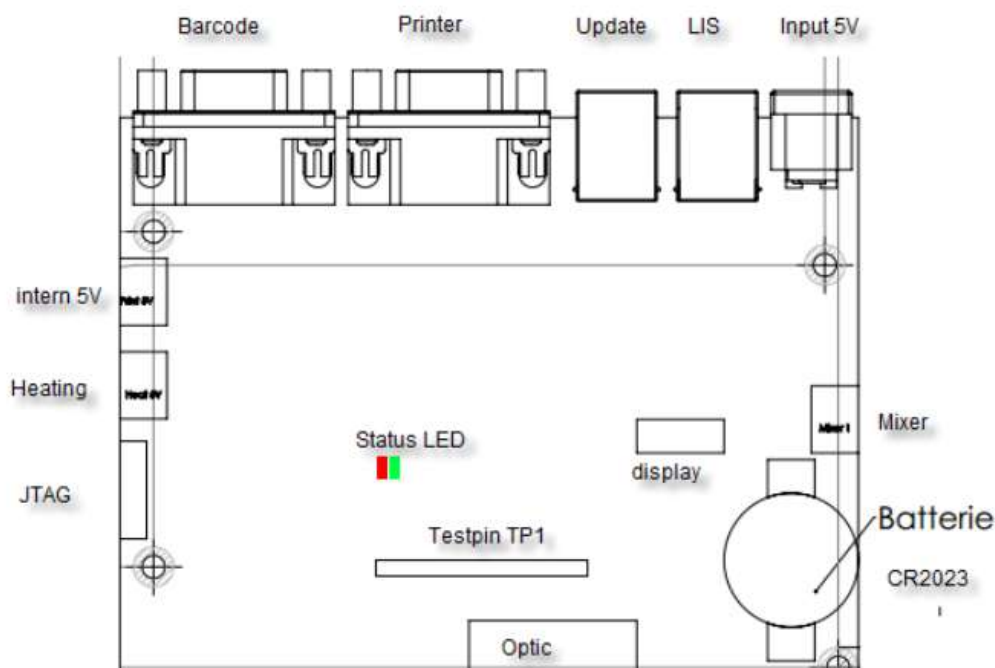
1. Porniți dispozitivul și așteptați aprox. 15min până când sistemul afișează 37 ° C pe ecran.
2. Umpleți un tub / flacon de reactiv cu 2 ml de apă și așezați-l într-o poziție de reactiv. Plasați un termometru digital în tubul de reactiv și lăsați să se încălzească timp de aproximativ 10 minute.
3. Apăsați meniul

Schimbați temperatura sistemului curent la valoarea termometrului. Așteptați 10 min și repetați procedura.

Problemele tipice:

Defecțiunea/Eroarea	Cauza posibilă	Măsurări
Încălzirea sistemului nu a ajuns la 37°C	Calibrarea senzorului este dincolo de spectrul stabilit	Resetați la implicit din fabrică ca descris în capitolul „Funcție ascunsă”
Sistemul arată 0.00°C	Senzorul a ieșit din diapazon	Temperatura mediului trebuie să fie de 0 – 45°C.
Placa cu senzor sau cu LED optic este defectă	Înlocuiți placa LED	

### 5.4 PREZENTAREA GENERALĂ AL PLĂCII PRICIPALE



Statutul după becul LED:

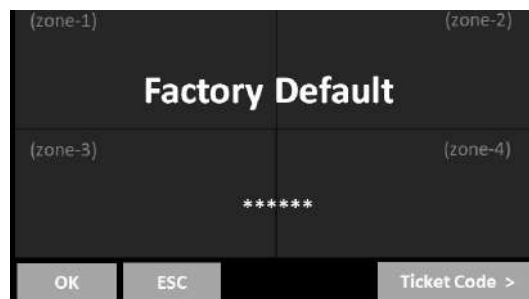
verde permanent	= totul este bine
roșu, permanent	= EEPROM eroare
verde, intermitent	= eroarea bateriei
roșu, intermitent	= senzor de temperatură/optica nu este conectată

## 6. FUNCȚIILE ASCUNSE

### 6.1 RESETAREA LA STAREA DIN FABRICĂ



IMAGINEA 19: ECRANUL DE START



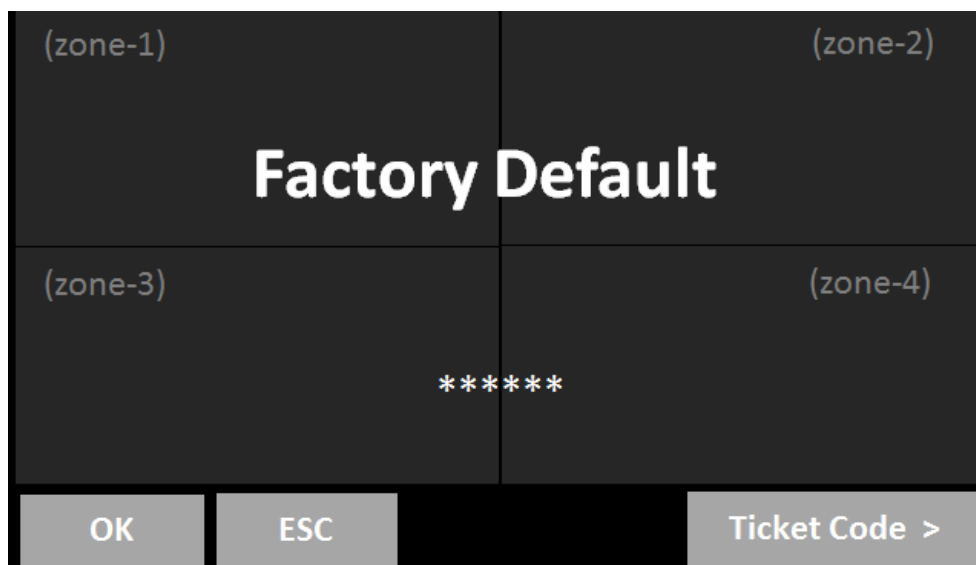
IMAGINEA 20: SETĂRILE IMPLICITE

Apăsați  
spinerul timp  
de 3 sec

Cum se resetează calibrarea PT la setările implicite de fabrică:

1. Porniți dispozitivul și treceți la ecranul de pornire
2. Atingeți orice buton de testare
3. Schimbați testul în „PT” și atingeți „Configurare” sau scanați codul de bare al flaconului PT
4. Introduceți LOT, data expirării și selectați Unități în „% + INR”

## 6.2 LOGAREA ÎN CALITATE DE ADMINISTRATOR



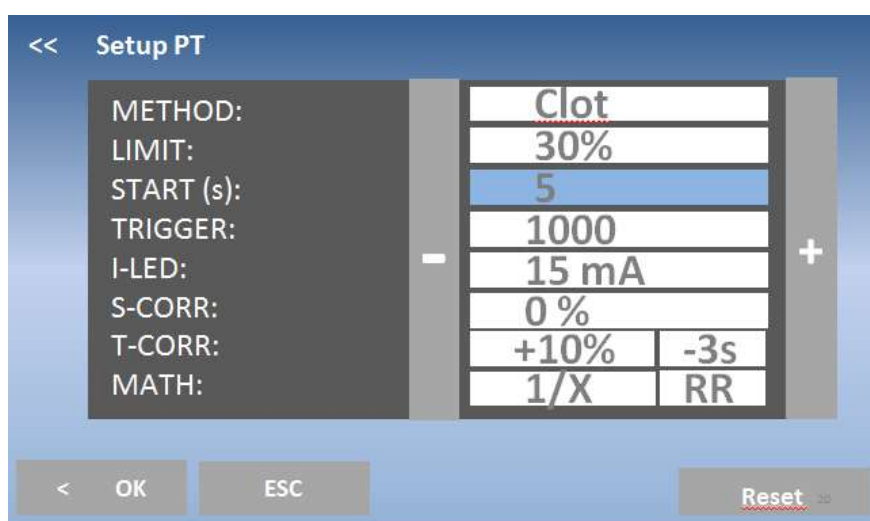
IMAGINEA21 : LOGAREA ÎN CALITATE DE ADMINISTRATOR

1. Ecran de întâmpinare: Apăsați lung pe pictograma filetului
2. Alternativa tactilă:      zona 1, 2, 1, 2, 1, 2

Ca admin funcțiile următoare sunt activate:

- Schimbă protocolul de testare (vezi următorul capitol)

## 6.3 MODIFICAREA PROTOCOLULUI DE TESTARE



IMAGINEA 22: PROTOCOLUL DE TESTARE

## 7. CURĂȚIREA ȘI MENTENANȚA

### 7.1 INFORMAȚIA GENERALĂ CU PRIVIRE LA CURĂȚIRE

- Curățați cu o cârpă sau un stick de bumbac fără scame.
- Nu purificați niciodată lichidul în zona optică sau de lucru.
- Păstrați dispozitivul fără praf și umezeală.
- Dacă dispozitivul este murdar cu lichide, îndepărtați murdăria cu o cârpă absorbantă.
- Dacă un lichid a fost vărsat sau pipetat accidental într-un canal de măsurare, deconectați imediat de la sursa de alimentare și curățați canalul de măsurare cu pipeta și o cârpă fără scame. Verificați funcția opticii din meniul DESERVIRE.



Aveți în vedere toate suprafețele și materialele, care ar putea fi în contact cu plasma sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.



Evitați orice contact direct cu decontaminanți sau dezinfectanți.

### 7.1 CURĂȚIREA

- Folosiți detergent, apă și înălbitor diluat 10% sau decontaminant comercial.
- Curățați și ștergeți toate deversările din jurul zonei de lucru sau ale sistemului de pompare cu ac cu detergent și apă.

### 7.2 DECONTAMINAREA

- Utilizați înălbitor diluat cu 30% și dezinfectant comercial (de exemplu, Bacillo® AF)
- Decontaminați zona de lucru, zona acului, rafturile pentru pacienți, tastatura, ecranul LCD, carcasele față, imprimanta și sertarele pentru deșeuri

### 7.3 MENTENANȚA REGULATĂ

- Curățați dispozitivul după fiecare utilizare
- Decontaminați dispozitivul în fiecare săptămână sau înainte de expediere pentru reparare / aruncare
- După 5 ani înlocuiți bateria plăcii de bază (CR2032)

## 8. ELIMINAREA ERORILOR

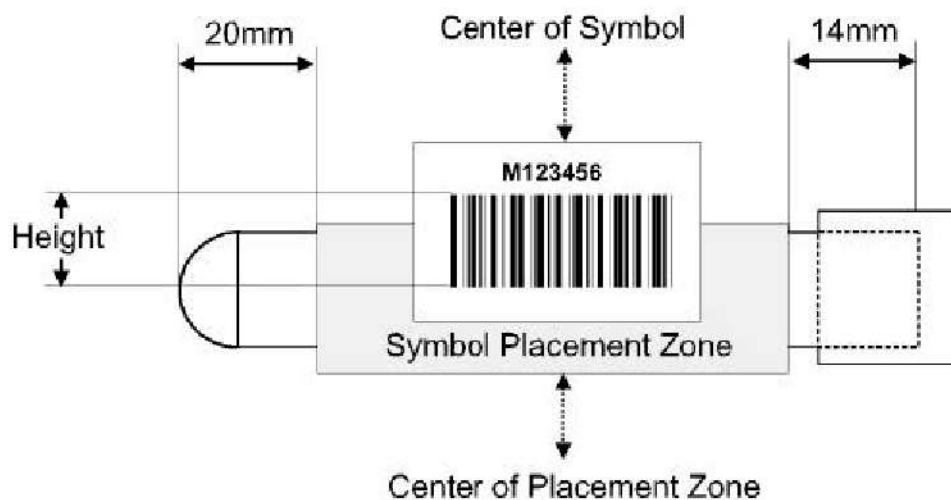
### 8.1 ERORILE DE MĂSURARE

Eroarea	Cauza posibilă	Măsurarea
Rezultatele marcate "*"	Rezultate ce trec peste limita de calibrare	
Marcă "T"	Temperatura dincolo de 36 – 38°C	
Marcă "E"	Reagentul este expirat	
Marcă "S"	Semnalul optic este foarte scăzut, din cauza turbidității extreme.	Verificați optica Evitați interferențele optice probe lipemice.
Marcă "f" sau "F" (doar testul PT)	Fibrinogen ridicat sau scăzut	Executați testul FIB pentru confirmare
Marcă "X"	Valorile duble deviază cu mai mult de 15%	
Marcă "+++"	Nu a fost observată nici o coagulare cu timpul de măsurare	

- Problemă cu pornirea automată ! (Pipetați spre centru, reduceți sau măriți declanșarea autostartului ).

## 9. ANEXĂ

### 9.1 GHIDUL CODULUI DE BARE



Specificația etichetei:

- Lungimea: 50 – 70 mm
- Lățimea: 20 - 30 mm
- Lungimea codului de bare: 40 – 60 mm
- Lățimea codului de bare: 10 - 20 mm
- Zona goală: > 5mm
- Rezoluția/modul: 5 -20mils (0.2 – 0.5mm)
- Diapazon: minim 1:2,5 to 1:3 (coduri bidimensionale)
- Calitate: Nivelul A sau B în conformitate cu ANSI X3.192 -1990

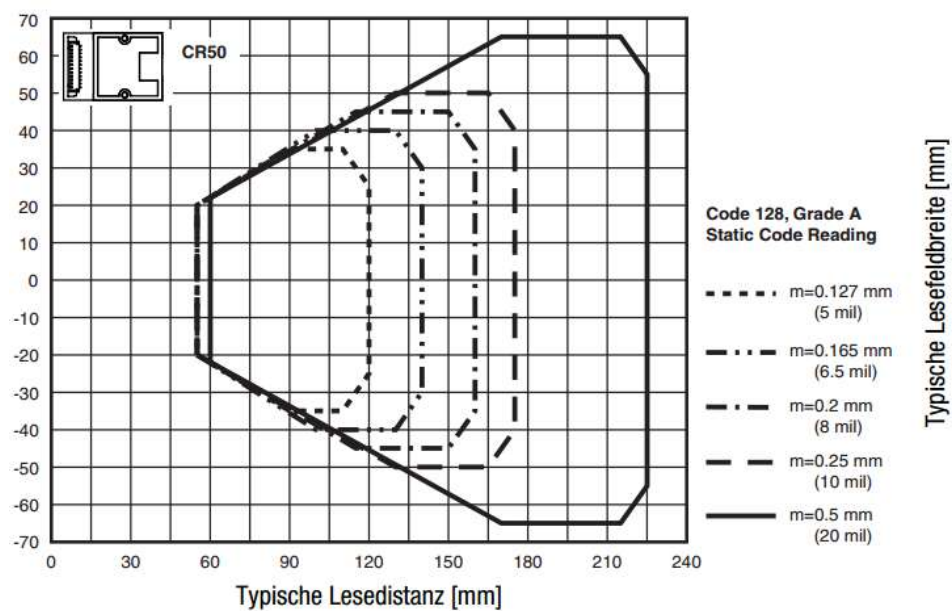
Coduri acceptate:

- Code 128 3 – 16 caractere
- EAN 128 3 – 13 caractere
- Code 39 4 – 13 caractere
- Code 93 4 – 13 caractere
- 2/5 intercalat 8 - 12 caractere



Câmpul de detecție:

Cea mai bună distanță de etichetă și scaner este de 80 - 120mm



## 9.2 SPECIFICAȚIILE TEHNICE

### Analizator

Ecran	Ecran tactil TFT 4.3" 480x272
Sistemul de măsurare	1-4 canale de măsurare independente lungimea de undă a LED-ului 405 nm
Cuvete	Cuva cu un singur canal pentru detectarea optică
Poziții (pre-încălzite)	5 poziții ale reagentului la 36.5 – 37.5 °C 20 poziții ale cuvetelor la 36.5 – 37.5°C
Volumele de reacție	Volumul minim total 75 µl
Aprobări	Analizatorul corespunde cu 98/79/EC (IVDD)

### Scanerul codului de bare

Scaner CCD	Energie maximă = 120mA Perioada de pulsație = 330/s
Clasa B EN 55022:2010 , EN 62471:2008	Lungimea de undă = 617 nm Cea mai bună distanță = 80 -120mm
Codec-ul acceptat	EAN (8,13, 128), Codul (39,93,128), Codabar, Intercalat 2 din 5

### Sursa de energie

Voltajul nominal de intrare	100 – 240VAC , 47-63Hz
Curentul maxim de intrare	0.7A rms
Energia de ieșire	5Vdc , 3.3A
Bateria (placa de bază)	Lithium CR2032 3V
Consumul de energie	max. = 14W    așteptare < 0.5W

### Dimensiuni

Dimensiuni (W x D x H)	225 x 150 x 90 mm
Greutatea	1.04 kg (fără sursa de energie)

### Condițiile de mediu

Temperatura de operare	15 - 30 °C
Umiditatea	< 70% umiditate relativă
Ridicarea deasupra nivelului mării	< 3.000m
Liber de praf	Gradul 2
Rezistența la impact	În conformitate cu IEC/EN 61010-1, 8.2.2
Nu sunt permise	Vibrațiile, expunerea la razele directe ale soarelui sau condițiile de aer.
Condițiile de păstrare	0°C - +40°C maxim 12 luni în ambalajul original
Condițiile de transport	0°C - +40°C

### Zgomot

Zgomotul de operare	Maxim 50 dBA
---------------------	--------------

**Interfețe**

RS232 (Codul de bare)	Sub-D9, feminin; 9600 Baud/8/1/N; Pin-9 alimentat cu 5V DC. Pentru scanere externe de coduri de bare portabile, imprimante în serie
RS232 (Printer)	Sub-D9 feminin; 9600 Baud/8/1/N; pentru imprimante în serie
USB (Service, Firmware Update)	Tip-B, feminin, 115200 Baud/8/1/N
USB (LIS)	Tip-B, feminin, 115200 Baud/8/1/N; Pentru comunicarea LIS

**Date tipice de performanță**

Testul	CV.	Spectrul
PT	<3%	0-30 INR
APTT	<3%	15 – 420 s
FIB	<7%	50-999 mg/dL



IVD

REF

A0230-010, A0230-040, A0230-100,

**Intended Use**

This product is used for the determination of prothrombin time (PT) in plasma according to Quick<sup>1,2</sup>. The test is sensitive to the extrinsic pathway coagulation factors II, V, VII, X and fibrinogen and therefore used for oral anticoagulant therapy with Vitamin-K inhibitors like Warfarin or Marcumar and also for the quantitative determination of extrinsic coagulation factors. The PT measures the extrinsic clotting time (factor VII activation) of test plasma after the addition PT reagent.

**Contents & Determinations**

Product	TECLOT PT-S	TECLOT PT-S	TECLOT PT-S
Cat.No.	A0230-010	A0230-040	A0230-100
PT-S Reagent*	5x2 mL	10x4 mL	10x10 mL

**Determinations**

Coatlon M**	200 Det.	800 Det.	2000 Det.
Coatlon A4	100 Det.	400 Det.	1000 Det.
Coatlon A6	200 Det.	800 Det.	2000 Det.

\*contains an extract of Rabbit brain with buffer, stabilizers and Calcium chloride.

\*\*Micro method (75µL in total)

**Preparation**

Reconstitute with high purity water with the volume stated on the vial label.

A0230-010	A0230-040	A0230-100
2 mL	4 mL	10 mL

Let stand at room temperature with occasional swirling for at least 15 min. Then place reagent into instrument and let incubate for further 15 min. The reagent sediments and must be swirled before each testing. On Coatlon instruments, you can use a mixing bar for this.

**Storage & Stability**

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

	2-8 °C	20-25 °C	37°C
PT Reagent	5 days	36 hours	8 hours

**Precautions**

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV, HCV. However products from human blood should be considered as potentially infectious.

**Specimen collection and storage<sup>4</sup>**

- Obtain venous blood by clean vein puncture.
- Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
- Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
- Separate plasma after centrifugation and store in plastic or siliconised glass tube.
- Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 30d at -20°C 6m at -70°C

**Procedure****A. Automated Method: Coatlon A**

Prothrombin Time		A4		A6	
PAT	Patient	50µl	CP1	25µl	CP1
BUF	IBS Buffer	0µl	P39	0µl	P79
CLR	-	0µl	-	0µl	-
DP	-	0µl	P00	0µl	P00
R0	-	0µl	P00	0µl	P00
R1	-	0µl	P00	0µl	P00
R2	PT Reagent	100µl	P25	50µl	P46

**B. Manual Method: Coatlon M system**

- Incubate PT reagent at 37°C for at least 10 minutes
- Pipette **25 µl of sample** into a test cuvette. Incubate at 37°C for 1-2 minutes.
- Add **50 µl of PT reagent** (37°C) and simultaneously start test.
- Record the clotting time in seconds.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

**Expected Results**

Typical seconds: 11 – 18 sec  
Normal range: 70 - 130% 0.85 – 1.15 INR

However results are influenced by instruments, technique, calibration etc. Each laboratory is recommended to establish its own range on the specific instrument used.

**Standardisation and Calibration**

The PT result is expressed as seconds or activity (% Quick) or INR (International Normalised Ratio).

**INR results:**

were calculated from normal time and ISI value (international sensitivity index). First is obtained by running fresh plasma from a pool of healthy individuals. The ISI value is stated in the LOT specific certificate of analysis.

$$INR = \left( \frac{Patient\ PT}{Normal\ PT} \right)^{ISI}$$

**Activity % (Quick) result:**

were calculated from a calibration curve, which is prepared from reference plasma (e.g. TECAL N) and dilutions in saline solution like 0.9% NaCl<sub>2</sub> or TECLOT IBS buffer. At least three or more calibration points are recommended. The calibration curve must be confirmed with control plasma in normal and abnormal range.

% of normal	100%*	50%	25%	12.5%**
diluted in saline	not dil.	1+1	1+3	1+7

\*The median of at least 21 healthy individuals is defined as 100%<sup>5</sup>

\*\*12.5% dilution may cause "+++" results in some cases, because the level of fibrinogen is too high diluted for optical detection.

**Quality Control**

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

**Limitations**

Great care must be taken to minimize variations which may occur by seemingly insignificant factors.

**A. Specimen Collection. AVOID:**

- Use only plastic tubes or siliconised glass.
- Delayed mixing of blood with anticoagulant.
- Contamination with tissue thromboplastin.
- Improper ratio of anticoagulant with blood.
- Hemolyzed, icteric or lipemic samples may interfere optical systems

**B. Laboratory Techniques**

- Perform tests at 37°C.
- Use only high purity water.
- Optimum pH is 7.0-7.5.
- ISI value is not constant within the first 30 min after reconstitution.
- Reagent sediments and must be swirled before each testing.

**Performance Characteristics****Typical performance on instrument Coatlon M4**

**Precision:** CV% (within run) CV% (inter-runs)  
Normal control < 3,0 < 5,0  
Abnormal control < 3,0 < 5,0

**Warranty**

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

**References**

- Quick, A.J., The Hemorrhagic Diseases and the Physiology of Hemostasis. Charles C. Thomas: Springfield, IL. 1942.
- Quick, A.J., Hemorrhagic Diseases. Lea and Febiger: Philadelphia. 1957.
- Miale, J.B., Laboratory Medicine-Hematology, 4th Edition. C.V. Mosby: St. Louis. 1972.
- National Committee for Clinical Laboratory Standards: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays.
- Besselaar A M H P van den, Lewis SM, Mannucci P n Poller L. 1993. Status of present and candidate International Reference Preparations (IRP) of thromboplastin for prothrombin time. Thromb Hemostas 69: 85
- Besselaar A M H P van den. 1991. The significance of the International Normalized Ratio (INR) for oral anticoagulant therapy. H17CC 3; 146153.

**Symbol keys**

	Expiry date		In Vitro Diagnostica		Biological hazard		Catalogue Number		Reconstitute with dest. water		Consult accompanying documents
	Store at 2-8°C		EU conformity		Manufacturer		Lot. Number		Ready to use		Authorized Representative





IVD

REF

A0300-025, A0300-050, A0320-050, A0320-100

**Intended Use**

This product is intended for determination of Activated Partial Thromboplastin Time (APTT) using silicate as activator. The determination of the APTT is used for the global evaluation of the intrinsic pathway and detecting deficiencies of the intrinsic coagulation factors VIII, IX, XI, XII, and Fletcher Factor as well as for monitoring heparin anticoagulant therapy or other coagulation methods where an APTT reagent is required<sup>1,2</sup>. The APTT reagent in the kit contains phospholipids and silica to ensure a highly consistent and stable product<sup>3</sup>. The APTT reagent is lupus anticoagulant insensitive. Lupus anticoagulant insensitive reagents yield more reliable factor assay results than reagents, which are sensitive to lupus inhibitors<sup>4</sup>. Prolonged clotting times may be observed in the following situations: deficiency of intrinsic coagulation factors, presence of heparin, in liver diseases, vitamin K Deficiency or other anticoagulants, which affect the intrinsic pathway.

**Contents & Determinations**

Product	TECLOT APTT-S Kit-25	TECLOT APTT-S Kit-50	TECLOT APTT-S A0300-050	TECLOT APTT-S A0320-100
Cat.No.	A0300-025	A0300-050	A0320-050	A0320-100
APTT-S Reagent*	5x5 mL	5x10 mL	10x5 mL	10x10 mL
CaCl <sub>2</sub> 0.025M**	5x5 mL	5x10 mL	-	-

**Determinations**

Coatlon M***	1000 Det.	2000 Det.	2000 Det.	4000 Det.
Coatlon A4	500 Det.	1000 Det.	1000 Det.	2000 Det.
Coatlon A6	1000 Det.	2000 Det.	2000 Det.	4000 Det.

\*APTT-S Reagent contains colloidal silicate with phospholipids, buffer and preservatives.

\*\*CaCl<sub>2</sub> contains sodium azide.

\*\*\*Micro method (75µL in total)

**Preparation**

Components of kit are ready to use. Allow CaCl<sub>2</sub> to prewarm 15 min at 37 °C and mix APTT reagent gently prior usage

**Storage & Stability**

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

	2-8 °C	20-25 °C	37 °C
APTT-S Reagent	30 days	8 days	8 hours

**Precautions**

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV, HCV. However products from human blood should be considered as potentially infectious.

**Specimen collection and storage<sup>5</sup>**

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

**Procedure****A. Automated Method: Coatlon A**

APTT-S	A4	A6		A4	A6		A4	A6
PAT Patient	50µl	CP1	25µl	CP1		Incubation	180s	
BUF -	0µl	P00	0µl	P00		Maxtime	180s	
CLR -	0µl	-	0µl	-		Unit	17	
DP -	0µl	P00	0µl	P00		Method	Coag	
R0 -	0µl	P00	0µl	P00		Math	-	
R1 APTT-S	50µl	P31	25µl	P60		CT-Mech	No	
R2 CaCl <sub>2</sub> 25mM	50µl	P26	25µl	P47		Deadtime	17s	
						SENS	1	
						POINTS	0	
						MIX	No	
						Clean	0	0
						Multi	1	3
						S-Corr	0%	
						T-Corr	15% - 6s	

**B. Manual Method: Coatlon M**

1. Prewarm CaCl<sub>2</sub> (0.025M) at 37°C for at least 10 min
2. Pipette 25 µl of sample into a test cuvette. Prewarm at 37°C for 1-2 minutes.
3. Add 25 µl APTT-S reagent and incubate exactly for 3 min at 37°C.
4. Add 25 µl of CaCl<sub>2</sub> (0.025M) and simultaneously start test.
5. Record the clotting time in seconds.

**Expected Results**

Typical normal results are 27-42 sec. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

**Quality Control**

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

**Limitations****A. Specimen Collection. AVOID:**

1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfere optical systems

**B. Laboratory Techniques**

1. Perform tests at 37°C.
2. Use only high purity water.
3. Optimum pH is 7.0-7.5.

**Performance Characteristics****Typical performance on instrument Coatlon M4**

**Precision:** CV% (within run) CV% (inter-runs)

QC control <3,0 <5,0

**Factor & Heparin sensitivity:**

Factor (%)	APTT Clotting time (s)		
	FVIII	FIX	FXI
<1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	358

Heparin (U/mL)	0 U/mL	0,2 U/mL	0,4 U/mL
APTT clotting time (s)	35	70	180

These values should be used as guidelines only. Each laboratory should establish factor or heparin sensitivity using its own instruments and techniques.

**Warranty**

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

**References**

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol* 36, 212-219 (1961).
2. Triplett DA, Harms CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol* 70, 556-569 (1978).
3. Stevenson KJ, Easton AC, Thomson JM, Poller L. The reliability of activated partial thromboplastin time methods and the relationship to lipid composition and ultrastructure. *Thromb Haemost* 55, 250-258 (1986).
4. Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis* 25, 98-105 (1995).
5. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays

Symbols key:

	Expiry date		In Vitro Diagnostica		Biological hazard		Catalogue Number		Consult accompanying documents
	Store at 2-8°C		EU conformity		Manufacturer		Lot. Number		Authorized Representative





IVD

REF

A0501-010, A0501-025, A0511-020, A0511-050

**Intended Use**

The TEClot FIB is intended for the quantitative determination of fibrinogen in human plasma according to method developed by Clauss.<sup>1</sup> Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use<sup>2</sup>. Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenemia (no detectable fibrinogen), hypofibrinogenemia (<1 mg/ml) and dysfibrinogenemia (abnormal fibrinogen molecule).

**Contents & Preparation**

Product	TEClot FIB Kit-10	TEClot FIB Kit-25	TEClot FIB	TEClot FIB
Cat.No.	A0501-010	A0501-025	A0511-020	A0511-050
Thrombin Reagent	5x2 mL	5x5 mL	10x2 mL	10x5 mL
IBS Buffer	1x125 mL	1x125 mL	-	-
TECal Normal	1x1 mL	1x1 mL	-	-
TEControl A	1x1 mL	1x1 mL	-	-

**Determinations**

Coatrom M*	400 Det.	1000 Det.	800 Det.	2000 Det.
Coatrom A4	200 Det.	500 Det.	400 Det.	1000 Det.
Coatrom A6	200 Det.	500 Det.	400 Det.	1000 Det.

\*Micro method (75µl in total)

- Thrombin Reagent:  
Contains bovine thrombin (~80NIH) with stabilizers  
REF: A0501-010/A0511-020: Reconstitute with 2mL purified water  
REF: A0501-025/A0511-050: Reconstitute with 5mL purified water
- IBS Buffer: Ready to use. Contains Imidazole buffered saline
- TECal Normal: Reconstitute with 1 mL purified water.  
Contains citrated human plasma.
- TEControl A: Reconstitute with 1 mL purified water.  
Contains citrated human plasma.



Swirl gently after reconstitution and allow standing for 15 minutes at room temperature. Mix well before use. Do not shake.

**Storage & Stability**

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

Thrombin Reagent*	2-8 °C	15-25 °C	37 °C
	12 days	5 days	24 hours
TEControl or Plasma	2-8 °C	15-25 °C	-20 °C
	8 hours	4 hours	30 days

\* Reagent must be protected from UV-light and evaporation

**Precautions**

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV, HCV. However products from human blood should be considered as potentially infectious.

**Specimen collection and storage<sup>3</sup>**

- Obtain venous blood by clean vein puncture.
- Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
- Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
- Separate plasma after centrifugation and store in plastic or siliconised glass tube.
- Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

**Procedure****A. Automated Method. Coatrom A**

Fibrinogen	A4	A6		A4	A6		A4	A6
PAT Patient	10µl	CP1	10µl	CP1	Incubation	0s	SENS	0
BUF IBS Buffer	90µl	P39	90µl	P79	Maxtime	120s	POINTS	4
CLR -	0µl	-	0µl	-	Unit	769	MIX	No
DP -	0µl	P00	0µl	P00	Method	Coag	Clean	1 3
R0 -	0µl	P00	0µl	P00	Math	log XY	Multi	1 1
R1 -	0µl	P00	0µl	P00	CT-Mech	Yes	S-Corr	0%
R2 Fibrinogen	50µl	P29	50µl	P49	Deadtime	3s	T-Corr	0%

**B. Manual Method: Coatrom M****1. Preparation of Standard, Control and Patient Dilutions**

Standard Dilution	Plasma	IBS Buffer
1:5	200µL Standard	800µL
1:10	500µL 1:5 STD	500µL
1:20	500µL 1:10 STD	500µL
1:40	500µL 1:20 STD	500µL
Patient or Control	100µL Plasma	900µL

2. Pipette **50 µl diluted standard or patient plasma** (1:10) into a test cuvette. Prewarm at 37°C for 1-2 minutes.

3. Add **25 µl Thrombin reagent** and simultaneously start test.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

**Calibration**

TECal Normal or other commercially prepared plasma standard in which Fibrinogen has been determined should be used as reference (200-300mg/dL). Plot the clotting time obtained with each of the FIB standard dilutions on the y-axis against the concentration of FIB (mg/dL) on the x-axis using log-log graph paper. The line of best fit should be determined by linear regression analysis. The fibrinogen in plasma samples can be determined by interpolation from the calibration curve.

**Expected Results**

Typical normal results are 180-450 mg/dL<sup>4,5</sup>. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

**Quality Control**

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylene tubes at -20°C is stable for 30 days

**Limitations****A. Specimen Collection. AVOID:**

- Use only plastic tubes or siliconised glass.
- Delayed mixing of blood with anticoagulant.
- Contamination with tissue thromboplastin.
- Improper ratio of anticoagulant with blood.
- Hemolyzed, icteric or lipemic samples may interfere optical systems

**B. Laboratory Techniques**

- Perform tests at 37°C.
- Use only high purity water.
- Optimum pH is 7.0-7.5.

**Performance Characteristics**

Precision:	CV% (within run)	CV% (inter-runs)
Normal control	< 5.0	< 5.0
Abnormal control	< 5.0	< 10.0

(Typical performance on instrument Coatrom M4)

**Warranty**

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

**References**

- Clauss, A., Gerinnungsphysiologische Schnellmethode zur bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
- Shaw, T.S., Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
- National Committee for the National Laboratory (NCCLS) Standards: Collection transport and preparation of blood specimens for coagulation testing and performance of coagulation assays. Document H21-A2, vol. 11, No. 23, 1991.
- Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37) : 37-48.
- Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6) : 196-201.

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





IVD

REF

A0501-010, A0501-025, A0511-020, A0511-050

**Verwendungszweck**

TECLOT FIB wird zur quantitativen Bestimmung von Fibrinogen im menschlichen Plasma nach einer von Clauss<sup>1</sup> entwickelten Methode verwendet. Der Fibrinogenpegel kann auf Grund von Entzündungen, Schwangerschaft und dem Gebrauch von Ovulationshemmern ansteigen<sup>2</sup>. Geringere Konzentrationen können bei verschiedenen Krankheiten wie Leberversagen und DIC auftreten. Angeborene Defizite beinhalten Afibrinogenämie (kein auffindbares Fibrinogen), Hypofibrinogenämie (<1 mg/ml) und Dysfibrinogenämie (abnormale Fibrinogenmoleküle).


**Inhalte und Vorbereitungen**

Produkt	TECLOT FIB Kit-10	TECLOT FIB Kit-25	TECLOT FIB A0511-020	TECLOT FIB A0511-050
Kat. Nr.	A0501-010	A0501-025	A0511-020	A0511-050
Thrombin Reagenz	5x2 mL	5x5 mL	10x2 mL	10x5 mL
IBS Puffer	1x125 mL	1x125 mL	-	-
TECAL Normal	1x1 mL	1x1 mL	-	-
TEControl A	1x1 mL	1x1 mL	-	-

**Bestimmungen**

Coatrom M*	400 Det.	1000 Det.	800 Det.	2000 Det.
Coatrom A4	200 Det.	500 Det.	400 Det.	1000 Det.
Coatrom A6	200 Det.	500 Det.	400 Det.	1000 Det.

\*Mikromethode (75µL insgesamt)

- Thrombin Reagenz:  
Enthält Rinderthrombin (~80 NIH) mit Stabilisatoren.  
**REF: A0501-010/A0511-020:** mit 2ml hochreinem Wasser anlösen  
**REF: A0501-025/A0511-050:** mit 5ml hochreinem Wasser anlösen
- IBS Puffer:  
gebrauchsfertig, 125ml  
Enthält gepufferte Natriumchlorid Lösung, pH 7,3-7,4
- TECAL Normal:  
Mit 1ml hochreinem Wasser anlösen  
Enthält mit Zitrat versetztes menschliches Plasma.
- TEControl A:  
Mit 1ml hochreinem Wasser anlösen  
Enthält mit Zitrat versetztes menschliches Plasma. 

Nach der Anlösung vorsichtig leicht schwenken und bei Raumtemperatur 15 Minuten stehen lassen. Vor Gebrauch gut mischen. Nicht schütteln.

**Lagerung und Stabilität**

Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum haltbar. **Geöffnete Reagenzien:**

Thrombin Reagenz*	2-8 °C	15-25 °C	37 °C
	12 days	5 days	24 Std
TEControl oder Plasma	2-8 °C	15-25 °C	-20 °C
	8 Std	4 Std	30 Std

\* Reagenz muss vor UV-Licht und Verdunstung geschützt werden.

**Vorsichtsmaßnahme**

Haut- & Augenkontakt vermeiden. Abfälle gemäß lokaler Richtlinien für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös behandelt werden.

**Probenentnahme und Lagerung<sup>3</sup>**

- Verfüßtes Blut mittels Venenpunktur unter sauberen Bedingungen entnehmen.
- Sofort 9 Teile Blut mit einem Teil 3,2% Natriumzitrat (0,105M) gut mischen.
- Probe bei 1500g 10 Minuten lang zentrifugieren (Thrombozyten <10000/µl)
- Plasma nach der Zentrifugierung entfernen und in einem Röhrchen aus Plastik oder silikonisiertes Glas aufbewahren.
- Plasma innerhalb von 4 Stunden verwenden, andernfalls gefroren lagern und kurz vor Gebrauch auftauen.

**Verfahren****A. Automatenmethode: Coatrom A**

Fibrinogen	A4	A6		A4	A6		A4	A6
PAT Patient	10µl	CP1	10µl	CP1	Incubation	0s	SENS	0
BUF IBS Buffer	90µl	P39	90µl	P79	Maxtime	120s	POINTS	4
CLR -	0µl	-	0µl	-	Unit	769	MIX	No
DP -	0µl	P00	0µl	P00	Method	Coag	Clean	1 3
R0 -	0µl	P00	0µl	P00	Math	log XY	Multi	1 1
R1 -	0µl	P00	0µl	P00	CT-Mech	Yes	S-Corr	0%
R2 Fibrinogen	50µl	P29	50µl	P49	Deadtime	3s	T-Corr	0%

Erklärung der Symbole:

	Verfallsdatum		In-Vitro Diagnostik		Biologische Gefahr		Katalog-Nummer		Begleitpapiere beachten
	Bei 2-8°C lagern		EU Konformität		Hersteller		Lot. - Nummer		Bevollmächtigter

**B. Manuelle Methode: Coatrom M**

- Vorbereitung von Standard-, Kontroll- und Patientenlösungen

Standardlösung	Plasma	IBS Puffer
1:5	200µL Standard	800µL
1:10	500µL 1:5 STD	500µL
1:20	500µL 1:10 STD	500µL
1:40	500µL 1:20 STD	500µL
Patient oder Kontrolle	100µL Plasma	900µL

- 50µL verdünntes Standard- oder Patientenplasma (1:10) in eine Küvette pipettieren. Bei 37°C für 1-2 Minuten erwärmen
  - 25µL Thrombinreagenz hinzufügen und gleichzeitig Test starten.
- Wenn Sie ein anderes Gerät verwenden, lesen Sie bitte für genauere Informationen die entsprechende Geräteanleitung.

**Kalibrierung**

TECAL Normal oder anderes kommerzielles Standardplasma, mit bekanntem Fibrinogengehalt, sollte als Referenz (200-300 mg/dl) verwendet werden. Geben Sie die Gerinnungszeit jeder FIB Standard Lösung auf der Y- Achse gegen die FIB Konzentration (mg/dl) auf der X- Achse an. Verwenden Sie Millimeterpapier. Die Reihe der besten Ergebnisse sollte durch lineare Regressionsanalyse bestimmt werden. Fibrinogen in den Plasmaproben kann durch Interpolation der Kalibrierungskurve bestimmt werden.

**Erwartete Ergebnisse**

Typische normale Ergebnisse sind 180-450mg/dl<sup>4,5</sup>. Die Ergebnisse sind jedoch von der Methode, wie die Gerinnungszeit bestimmt wird, abhängig und können von Labor zu Labor variieren. Jedem Labor wird empfohlen, seinen eigenen normalen Ergebnisbereich auf dem verwendeten Instrument zu erstellen.

**Qualitätskontrolle**

TEControl oder anderes kommerzielles Kontrollplasma sollte, um eine gute Qualität sicherzustellen, in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. In regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. TEControl kann einmalig wieder eingefroren werden. Hierfür 120-150µL in einem verschließbaren polypropylen Gefäß bei -20°C aufbewahren und innerhalb der nächsten 30 Tage verwenden.

**Beschränkungen**

A. Probenvorbereitung. Achten Sie auf:

- nur Plastikröhrchen oder silikonisiertes Glas verwenden
- verzögertes Mischen von Blut mit Antikoagulanzen vermeiden
- Kontamination mit Gewebethromboplastin vermeiden
- falsches Verhältnis von Antikoagulanzen und Blut vermeiden
- Hämolytische, lipämische oder ikterische Proben können optische Systeme stören

B. Labortechniken

- Tests bei 37°C durchführen
- nur hochreines Wasser verwenden
- der optimale pH Wert ist 7,0-7,5

**Leistungsdaten**

<b>Präzision:</b>	VK% (Einzellauf)	VK% (Mehrfachlauf)
Normale Kontrolle	< 5,0	< 5,0
Abnormale Kontrolle	< 5,0	< 10,0

(Typische Leistung beim Gerät Coatrom M4)

**Garantie**

Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußerlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

**Referenzen**

- Clauss, A., Gerinnungsphysiologische Schnellmethode zur Bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
- Shaw, T.S., Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
- National Committee for the National Laboratory (NCCLS) Standards: Collection transport and preparation of blood specimens for coagulation testing and performance of coagulation assays. Document H21-A2, vol. 11, No. 23, 1991.
- Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37): 37-48.
- Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6): 196-201.





**Revisions-Übersicht:**

Rev.	am	Änderung durch	Gültig für	Freigabe am	Freigabe durch
1	5.4.11	WG	Technoclone FIB		
	Beschreibung:	New box insert for Technoclone FIB.			
2	21.12.11	CB	Technoclone FIB	21.12.11	CH
	Beschreibung:	Neue Stabilitätsangaben. Die Vorgaben wurden dem Technoclone Stability Test Report „TC6E0C.01“ vom 5.5.2010 entnommen.			
3	11.11.13	CB	Technoclone FIB		
	Beschreibung:	<ul style="list-style-type: none"> <li>- Protokoll für A4+A6</li> <li>- Stabilitätsdaten neu</li> </ul>			
4	16.10.17	AR	Technoclone FIB	16.10.17	CH
	Beschreibung:	Technoclone Puffer (A0591-090) wird ersetzt durch IBS (A0590-125) (wegen deutlicher Messunterschiede bei Coatron A und X Serie) Werteermittlung für das CoA erfolgt ebenso mit IBS (A0590-125)			
5	23.01.18	VG	Technoclone FIB	23.01.18	VG
	Beschreibung:	Neue Stabilitätsangaben von Technoclone vom Thrombin Reagent.			



IVD

REF

A0590-125

## Intended Use

The IBS Buffer solution is optimally formulated for use on Coagulation Analyzers. Use in accordance with the recommended Operators Manuals for installing and replacing Owrens Veronal Buffer (OVB). The IBS can be used as the diluent for preparing plasma dilutions in the performance of Fibrinogen determinations and Coagulation Factor Assays with all manual, mechanical, or photo-optical means of clot detection. Follow Reagent manufacturer's recommended procedures for preparation of plasma dilutions using Imidazole Buffered Saline.

## Contents & Determinations

Product	IBS Buffer
Cat.No.	A0590-125
IBS Buffer	1x125 mL

## Preparation

IBS: pH 7.3 - 7.4, liquid  
Ready to use.

## Storage and Stability

Unopened reagents are stable until the expiration date shown on the label stored at 2-8°C.

## Precautions

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.

## Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





IVD

REF

A0590-125

## Verwendungszweck

Die IBS Pufferlösung (Imidazole Buffered Saline) wird für die Verdünnung von Plasma verwendet werden, wie es z.B. bei der koagulometrischen Bestimmung von Fibrinogen, Einzelfaktoren oder auch Verdünnungsreihen für die Methoden Kalibrierung notwendig ist.

## Inhalte und Bestimmungen

Produkt	IBS Puffer
Kat.Nr.	A0590-125
IBS Buffer	1x125 mL

## Vorbereitung

IBS: pH 7.3 - 7.4, flüssig  
Gebrauchsfertig

## Lagerung und Stabilität

Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum haltbar.

## Vorsichtsmaßnahmen

Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Bestandteile gemäß lokaler Vorschriften für infektiöse Materialien entsorgen.

## Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

Verfallsdatum	In-Vitro Diagnostik	Biologische Gefahr	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	EU Konformität	Hersteller	Lot. - Nummer	Bevollmächtigter





IVD

REF

A0320-050

**Intended Use**

Clotting test for quantitative determination of the Activated Partial Thromboplastin Time (APTT) in citrated human plasma using silicate as contact activator for factor XII. Intended to be used by professional laboratory personnel using coagulation analysers. The determination of the APTT is used for the global evaluation of the intrinsic pathway and detecting deficiencies of the intrinsic coagulation factors VIII, IX, XI, XII, and Fletcher Factor or other coagulation methods where an APTT reagent is required<sup>1,2</sup>.

The APTT reagent in the kit contains phospholipids and silica to ensure a highly consistent and stable product<sup>3</sup>. The APTT reagent is lupus anticoagulant insensitive. Lupus anticoagulant insensitive reagents yield more reliable factor assay results than reagents, which are sensitive to lupus inhibitors<sup>4</sup>.

Prolonged clotting times may be observed in the following situations: deficiency of intrinsic coagulation factors, presence of heparin or other anticoagulants, which affect the intrinsic pathway and in liver diseases.

**Contents**

Product	TECLOT APTT-S
REF	A0320-050
APTT-S reagent	10x5 mL
Determinations*	2000

\*Micro method (75µL in total)

APTT-S reagent contains colloidal silicate with phospholipids, buffer and preservatives.

Recommended additional material (not included in package)

Auxiliary reagents	A0350-050 Calcium Chloride 0.025M, 10 x 5mL
Calibration	not required
Quality Control	P6001-010 TECControl N, 10 x 1mL P6101-010 TECControl A, 10 x 1mL

**Preparation**

Ready to use. Swirl APTT reagent gently prior usage

**Storage & Stability**

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

	2-8 °C	20-25 °C	37 °C
APTT-S Reagent	30 days	8 days	8 hours

**Precautions**

The reagent contains sodium azide (less than 0.1%) to prevent microbial growth. Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.

**Specimen collection and storage<sup>5</sup>**

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

**Procedure****A. Automated Method: Coatron A**

See application book of device

**B. Manual Method: Coatron X**

1. Prewarm **CaCl<sub>2</sub>** (0.025M) at 37°C for at least 10 min.
2. Pipette **25 µL of sample** into a test cuvette. Prewarm at 37°C for 1-2 minutes.
3. Add **25 µL APTT-S reagent** and incubate exactly for **3 min** at 37°C.
4. Add **25 µL of CaCl<sub>2</sub>** (0.025M) and simultaneously start test.
5. Record the clotting time in seconds.

**Expected Results**

Typical normal results are 27-42 sec. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

**Quality Control**

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TECControl can be frozen one time after reconstitution. 120-150 µL stored in closed polypropylene tubes at -20°C is stable for 30 days

**Limitations**

- A. Specimen Collection. AVOID:
  1. Use only plastic tubes or siliconised glass.
  2. Delayed mixing of blood with anticoagulant.
  3. Contamination with tissue thromboplastin.
  4. Improper ratio of anticoagulant with blood.
  5. Hemolyzed, icteric or lipemic samples may interfere optical systems
- B. Laboratory Techniques
  1. Perform tests at 37°C.
  2. Use only high purity water.
  3. Optimum pH is 7.0-7.5.
- C. Interfering substances
  1. Bilirubin 40mg/dL
  2. Haemoglobin 1000 mg/dL

**Performance Characteristics****Typical performance on instrument Coatron X**

**Precision:** CV% (within run) CV% (inter-runs)

QC control < 3,0 < 5,0

**Factor & Heparin sensitivity:**

Factor (%)	APTT Clotting time (s)		
	F VIII	F IX	F XI
< 1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	358

Heparin (U/mL)	0 U/mL	0,2 U/mL	0,4 U/mL
APTT clotting time (s)	35	70	180

These values should be used as guidelines only. Each laboratory should establish factor or heparin sensitivity using its own instruments and techniques.

**Warranty**

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

**References**

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol* 36, 212-219 (1961).
2. Triplett DA, Harms CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol* 70, 556-569 (1978).
3. Stevenson KJ, Easton AC, Thomson JM, Poller L. The reliability of activated partial thromboplastin time methods and the relationship to lipid composition and ultrastructure. *Thromb Haemost* 55, 250-258 (1986).
4. Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis* 25, 98-105 (1995).
5. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays

Symbols key:

	Expiry date		In Vitro Diagnostica		Biological hazard		Catalogue Number		Consult accompanying documents
	Store at 2-8°C		EU conformity		Manufacturer		Lot. Number		Authorized Representative





IVD

REF

A0320-050

**Verwendungszweck**

Dieses Produkt ist bestimmt für die quantitative Bestimmung der aktivierten partiellen Thromboplastinzeit (APTT) in humanen Citratplasma mit Hilfe von Silikat als Kontaktaktivator für Faktor XII. Die Anwendung ist bestimmt für medizinisches Fachpersonal und benötigt einen Gerinnungsanalyser.

Die Bestimmung der APTT dient der globalen Auswertung des intrinsischen Gerinnungssystems, sowohl zum Nachweis von Mängeln bei den intrinsischen Koagulationsfaktoren VIII, IX, XI, XII und Fletcher Faktor oder anderer Koagulationsmethoden, bei denen ein APTT - Reagenz benötigt wird.<sup>1,2</sup>

Das APTT Reagenz in diesem Kit enthält Phospholipide und Silizium, um ein sehr widerstandsfähiges und stabiles Produkt zu gewährleisten<sup>3</sup>. Das Reagenz reagiert nicht auf Lupus Antikoagulanzen und liefert daher verlässlichere Ergebnisse bei Faktorbestimmungen<sup>4</sup>. Verlängerte Gerinnungszeiten können bei den folgenden Situationen beobachtet werden: Mangel an intrinsischen Koagulationsfaktoren, Vorhandensein von Heparin oder andere Antikoagulantien, die das intrinsische System beeinflussen und bei Lebererkrankungen.

**Inhalt**

Produkt	TECLOT aPTT-S
REF	A0320-050
aPTT-S Reagenz	10x5 mL
Bestimmungen*	2000

\*Micro Methode (75µL insgesamt)

Das APTT-S Reagenz enthält kolloidales Silikat mit Phospholipiden, Puffer und Konservierungsstoffe.

Zusätzlich notwendige Reagenzien (nicht in der Packung vorhanden)

Hilfsreagenzien	A0350-050 Calcium Chloride 0,025M, 10 x 5mL
Kalibration	Nicht notwendig
Qualitätskontrolle	P6001-010 TECControl N, 10 x 1mL P6101-010 TECControl A, 10 x 1mL

**Vorbereitung**

Das Reagenz ist gebrauchsfertig und muss vor dem Gebrauch leicht aufgemischt werden.

**Lagerung und Stabilität**

Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum stabil. Geöffnetes Reagenz:

	2-8 °C	20-25 °C	37°C
APTT-S Reagenz	30 Tage	8 Tage	8 Stunden

**Vorsichtsmaßnahmen**

Das Reagenz beinhaltet Natriumazid (< 0.1%). Augen und Hautkontakt vermeiden. Geeignete Schutzkleidung tragen. Abfall gemäß lokaler Bestimmungen für infektiöse Materialien entsorgen.

**Probenentnahme und Lagerung <sup>5</sup>**

1. Venöses Blut mittels Venenpunktur unter sauberen Bedingungen entnehmen.
2. Sofort 9 Teile Blut mit einem Teil 3,2% Natriumzitrat (0,105M) gut mischen.
3. Probe bei 1500g 10 Minuten lang zentrifugieren (Thrombozyten <100000/µl)
4. Plasma nach der Zentrifugierung entfernen und in einem Röhrchen aus Plastik oder silikonisiertes Glas aufbewahren.
5. Plasma innerhalb von 4 Stunden verwenden, andernfalls gefroren lagern und kurz vor Gebrauch auftauen.

Stabilität von Plasma: 4h bei 18-26°C 8h bei 2-8° 14d bei -20°C 6m bei -70°C

**Verfahren****A. Automatenmethode: Coatron A**

Siehe Applikationsbuch des Gerätes

**B. Manuelle Methode: Coatron X**

1. Kaliumchlorid (0,025M) mind. 10 Minuten lang bei 37°C erwärmen.
2. **25µl Probe** in eine Küvette pipettieren. Bei 37°C für 1-2 min vorwärmen.
3. **25µl APTT-S** Reagenz hinzufügen und für genau **3 min bei 37°C inkubieren**
4. **25µl CaCl<sub>2</sub>** (0,025M) hinzufügen und gleichzeitig Test starten.
5. Gerinnungszeit in Sekunden notieren.

**Erwartete Ergebnisse**

Typische normale Ergebnisse liegen bei 27-42 Sekunden. Jedoch sind die Ergebnisse von der verwendeten Methode der Gerinnungsbestimmung abhängig und können in verschiedenen Labors unterschiedlich ausfallen. Jedem Labor wird empfohlen, eine eigene Ergebnisreihe und den Normalbereich mit dem verwendeten Gerät zu erstellen.

**Qualitätskontrolle**

TEControl oder anderes kommerzielles Kontrollplasma sollte in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. TECControl kann einmalig wieder eingefroren werden. Hierfür 120-150µL in einem verschließbaren polypropylen Gefäß bei -20°C aufbewahren und innerhalb der nächsten 30 Tage verwenden.

**Vorschriften**

A. Probenvorbereitung. Achten Sie auf:

1. nur Plastikröhrchen oder silikonisiertes Glas verwenden
2. verzögertes Mischen von Blut mit Antikoagulanzen vermeiden
3. Kontaminierung mit Gewebethromboplastin vermeiden
4. falsches Verhältnis von Antikoagulanzen und Blut vermeiden
5. Hämolytische, lipämische oder ikterische Proben können optische Systeme stören

B. Labortechniken

1. Tests bei 37°C durchführen
2. nur hochreines Wasser verwenden
3. der optimale pH Wert ist 7,0-7,5

C. Interferenzen

1. Bilirubin: kein Effekt unter 40mg/dL
2. Hämoglobin: kein Effekt unter 1000mg/dL

**Leistungsdaten****Typische Leistungsdaten beim Gerät Coatron X**

<b>Präzision:</b>	VK% (Einzellauf)	CV% (Mehrfachlauf)
QC control	<3,0	<5,0

**Faktor & Heparin Empfindlichkeit:**

Faktor (%)	APTT Gerinnungszeit (s)		
	F VIII	F IX	F XI
< 1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	35

Heparin (U/mL)	0 U/mL	0,2 U/mL	0,4 U/mL
APTT Gerinnungszeit	35	70	180

Diese Werte sollen nur als Richtlinien verwendet werden. Jedes Labor sollte mit eigenen Instrumenten und Techniken Sensitivitätswerte erstellen.

**Garantie**

Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußerlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

**Referenzen**

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol* 36, 212-219 (1961).
2. Triplett DA, Hams CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol* 70, 556-569 (1978).
3. Stevenson KJ, Easton AC, Thomson JM, Poller L. The reliability of activated partial thromboplastin time methods and the relationship to lipid composition and ultrastructure. *Thromb Haemost* 55, 250-258 (1986).
4. Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis* 25, 98-105 (1995).
5. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays

Erklärung der Symbole:



Verfallsdatum



In-Vitro Diagnostik



Biologische Gefahr



Katalog-Nummer



Begleitpapiere beachten





IVD

REF

P6001-010

**Intended Use**

Use as a normal control for following coagulation tests:

**PT, APTT, Thrombin time, Fibrinogen,  
Anti-thrombin and D-Dimer**

**Contents**

10 x 1mL freeze dried citrate-anticoagulated human plasma

**Preparation**

Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B): Reconstitute individual vials with **1,7 ml** distilled water.

**Storage & Stability**

Unopened vials are stable until the expiration date shown on the label stored at 2°-8°C.

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C
1 month	8 hours	4 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

**Precautions**

This product contains substance from human origin!  
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

**Expected Results**

Refer to "Certificate of Analysis".

**Warranty**

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





IVD

REF

P6001-010

**Verwendungszweck**

Als normale Kontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit, Fibrinogen,  
Antithrombin und D-Dimer**

**Inhalt**

10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

**Vorbereitung**

Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TECLOT PT-B): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

**Lagerung und Stabilität**

Ungeöffnete Fläschchen sind bei Lagerung zwischen 2-8°C zum bis auf dem Etikett angegebenen Verfallsdatum haltbar.

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C
1 Monat	8 Stunden	4 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

**Vorsichtsmaßnahmen**

Dieses Produkt enthält Substanzen humanen Ursprungs! Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

**Erwartete Ergebnisse**

Lesen Sie das Analysenzertifikat

**Garantie**

Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

Verfallsdatum	In-Vitro Diagnostik	Biologische Gefahr	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	EU Konformität	Hersteller	Lot. - Nummer	Bevollmächtigter







IVD

REF

P6101-010

**Intended Use**

Use as an abnormal control for following coagulation tests:

**PT, APTT, Thrombin time, Fibrinogen,  
Antithrombin and D-Dimer**

**Contents**

10 x 1mL freeze dried citrate-anticoagulated human plasma

**Preparation**

Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B): Reconstitute individual vials with **1,7 ml** distilled water.

**Storage & Stability**

Unopened vials are stable until the expiration date shown on the label stored at 2°-8°C.

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C
1 month	8 hours	4 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

**Precautions**

This product contains substance from human origin!  
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

**Expected Results**

Refer to "Certificate of Analysis".

**Warranty**

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





IVD

REF

P6101-010

**Verwendungszweck**

Als abnormale Kontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit, Fibrinogen,  
Antithrombin und D-Dimer**

**Inhalt**

10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

**Vorbereitung**

Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

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Ungeöffnete Fläschchen sind bei Lagerung zwischen 2-8°C zum bis auf dem Etikett angegebenen Verfallsdatum haltbar.

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

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**Erwartete Ergebnisse**

Lesen Sie das Analysenzertifikat

**Garantie**

Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußerlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

Verfallsdatum	In-Vitro Diagnostik	Biologische Gefahr	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	EU Konformität	Hersteller	Lot. – Nummer	Bevollmächtigter

