



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



Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 104507 0003 Rev. 06

Manufacturer:

ACON Laboratories, Inc.

5850 Oberlin Drive, #340
San Diego CA 92121
USA

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

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

Report no.:

SH22743EXT01

Valid from:

2022-05-04

Valid until:

2025-05-26

Date,

2022-05-04

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

Full Quality Assurance System

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

No. V1 104507 0003 Rev. 06

Model(s):

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



EC Certificate

Full Quality Assurance System

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

No. V1 104507 0003 Rev. 06

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

Facility(ies):

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

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

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

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

Declaration of Conformity

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

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

Mission[®] Urinalysis Reagent Strips (U031-XX1)

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

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

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

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

Signed this 11 day of February, 2020
in San Diego, CA USA



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



Declaration of Conformity

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

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

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

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

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

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

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

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



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





ACON Laboratories, Inc.

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

November 11th 2016

CERTIFICATION LETTER

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

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

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

Sincerely

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

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

jalvarenga@aconlabs.com

+1 858 875 8085



Certificate

No. Q5 104507 0001 Rev. 03

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 104507 0001 Rev. 03

Report No.: SH22743A01

Valid from: 2022-09-15
Valid until: 2025-09-06

Date, 2022-09-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 104507 0001 Rev. 03

Applied Standard(s):

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

Facility(ies):

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

Address holder for registration only

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

Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

Storage of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

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

Design and Development of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

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

Manufacture of
blood glucose test strips, antigen rapid test and IgG/IgM antibody
rapid test for infectious disease.

STATEMENT

We, ACON Laboratories, Inc., having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* authorize SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*

to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: January 3, 2023

Signature:



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

Mission[®]

Urine Controls

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

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



Global Diagnostics for Local Markets™

Mission® Urine Controls

Reliable

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

Quick and Convenient Testing

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

Two Types of Urine Controls Available

Liquid Urine Control

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

Dry Strip Urine Control

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



Specifications

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

Ordering Information

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

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

We also offer other rapid diagnostic and medical products for:

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

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



Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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



Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

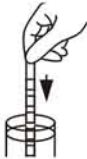
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

Flexible

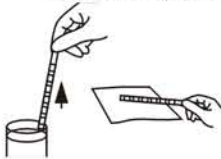
- Compatible for visual and analyzer reading
- More than 30 different combinations available

Multiple Packaging Options and Long Shelf Life

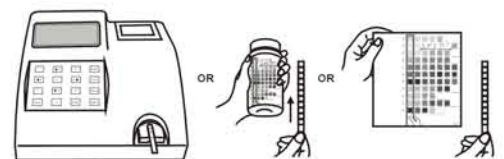
- Canister Packaging
 - Available in 25, 50, 100 and 150 strips per kit
 - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
 - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!*
 - Single-strip Pouch
 - Individually packaged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



Step 1: Immerse strip into urine



Step 2: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

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

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

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

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



U120 Urine Analyzer



Accurate

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

Reliable

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

Convenient Operation

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

Easy Data Management

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

Unique Lockout Functions *new!*

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

Specifications

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

Ordering Information

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

U500 Urine Analyzer



Accurate and Efficient

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

Easy to Operate

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

Convenient

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

Data Management Capability

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

Unique Lockout Functions Coming Soon!

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

Specifications

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

Ordering Information

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

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

† Cleared for US 510(k)



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 **1st 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.


Seal & Signature

Authority Person Name: **Steven Zhou**

Authority Person Position: **Regional Manager**

Date: **2023.12.13**



EC Declaration of Conformity

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

Ref. No.:20220513-A05

Manufacturer
(Name, Address)

Getein Biotech, Inc.
No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

Authorized Representative
(Name, Address)

CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Medical device

No.	Product Name
1	Getein 1100 Immunofluorescence Quantitative Analyzer
2	Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)
3	NT-proBNP Fast Test Kit (Immunofluorescence Assay)
4	hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)
5	NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)
6	CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
7	D-Dimer Fast Test Kit (Immunofluorescence Assay)
8	PCT Fast Test Kit (Immunofluorescence Assay)
9	CysC Fast Test Kit (Immunofluorescence Assay)
10	mAlb Fast Test Kit (Immunofluorescence Assay)
11	NGAL Fast Test Kit (Immunofluorescence Assay)
12	β 2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+ β Fast Test Kit (Immunofluorescence Assay)
15	H-FABP Fast Test Kit (Immunofluorescence Assay)
16	PCT/CRP Fast Test Kit (Immunofluorescence Assay)
17	CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)
18	HbA1c Fast Test Kit (Immunofluorescence Assay)
19	NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay)
20	CK-MB Fast Test Kit (Immunofluorescence Assay)
21	hs-cTnI Fast Test Kit (Immunofluorescence Assay)
22	T3 Fast Test Kit (Immunofluorescence Assay)
23	T4 Fast Test Kit (Immunofluorescence Assay)
24	TSH Fast Test Kit (Immunofluorescence Assay)
25	Scr Fast Test Kit (Immunofluorescence Assay)
26	PLGF Fast Test Kit (Immunofluorescence Assay)

- 27 HCY Fast Test Kit (Immunofluorescence Assay)
- 28 Anti-CCP Fast Test Kit (Immunofluorescence Assay)
- 29 25-OH-VD Fast Test Kit (Immunofluorescence Assay)
- 30 Lp-PLA2 Fast Test Kit (Immunofluorescence Assay)
- 31 FOB Fast Test Kit (Immunofluorescence Assay)
- 32 SAA Fast Test Kit (Immunofluorescence Assay)
- 33 H. pylori Fast Test Kit (Immunofluorescence Assay)
- 34 PRL Fast Test Kit (Immunofluorescence Assay)
- 35 Transferrin Fast Test Kit (Immunofluorescence Assay)
- 36 Insulin Fast Test Kit (Immunofluorescence Assay)
- 37 PG I /PG II Fast Test Kit (Immunofluorescence Assay)
- 38 LH Fast Test Kit (Immunofluorescence Assay)
- 39 FSH Fast Test Kit (Immunofluorescence Assay)
- 40 Anti-TP Fast Test Kit (Immunofluorescence Assay)
- 41 AFP/CEA Fast Test Kit (Immunofluorescence Assay)
- 42 AMH Fast Test Kit (Immunofluorescence Assay)
- 43 fT3 Fast Test Kit (Immunofluorescence Assay)
- 44 fT4 Fast Test Kit (Immunofluorescence Assay)
- 45 Total IgE Fast Test Kit (Immunofluorescence Assay)
- 46 Vit-B12 Fast Test Kit (Immunofluorescence Assay)
- 47 Prog Fast Test Kit (Immunofluorescence Assay)
- 48 Testosterone Fast Test Kit (Immunofluorescence Assay)
- 49 E2 Fast Test Kit (Immunofluorescence Assay)
- 50 RF Fast Test Kit (Immunofluorescence Assay)
- 51 ASO Fast Test Kit (Immunofluorescence Assay)
- 52 Ferritin Fast Test Kit (Immunofluorescence Assay)
- 53 ST2 Fast Test Kit (Immunofluorescence Assay)
- 54 CA125 Fast Test Kit (Immunofluorescence Assay)
- 55 CA19-9 Fast Test Kit (Immunofluorescence Assay)
- 56 CA15-3 Fast Test Kit (Immunofluorescence Assay)
- 57 RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)
- 58 Influenza A/B Fast Test Kit (Immunofluorescence Assay)
- 59 RSV Fast Test Kit (Immunofluorescence Assay)
- 60 IL-6 Fast Test Kit (Immunofluorescence Assay)
- 61 BNP Fast Test Kit (Immunofluorescence Assay)
- 62 SAA/CRP Fast Test Kit (Immunofluorescence Assay)
- 63 Folate acid Fast Test Kit (Immunofluorescence Assay)
- 64 hs-CRP Fast Test Kit (Immunofluorescence Assay)
- 65 TnT Fast Test Kit (Immunofluorescence Assay)
- 66 PCT/IL-6 Fast Test Kit (Immunofluorescence Assay)

67	HBP Fast Test Kit (Immunofluorescence Assay)
68	S100- β Fast Test Kit (Immunofluorescence Assay)
69	CK-MB/hs-cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
70	Cortisol Fast Test Kit (Immunofluorescence Assay)
71	CEA Fast Test Kit (Immunofluorescence Assay)
72	AFP/CEA Fast Test Kit (Immunofluorescence Assay)

Classification Other device (according to Annex II of the directive 98/79/EC)

Conformity assessment route Annex III of the 98/79/EC

Applicable	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
coordination	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
standards	EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015
	EN 61326-2-6:2006	IEC 61326-1:2013	
	EN 61010-2-101:2002	IEC 61010-1:2010	

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 I.

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 BSI Group The Netherlands B. V. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing
13th, May, 2022
 (place and date of issue)

(name and signature or equivalent marking of authorized person)



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

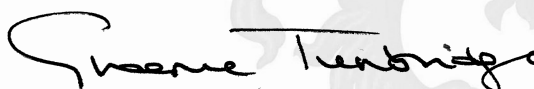
基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编: 211505

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



...making excellence a habit.™

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

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

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
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	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。
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	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. 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。

Original Registration Date: 2020-05-29

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A Member of the BSI Group of Companies.

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.



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

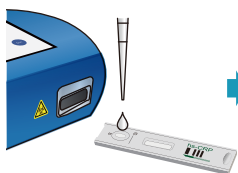
One-step test

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

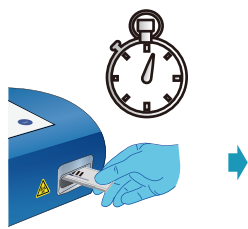


Result Show and Print

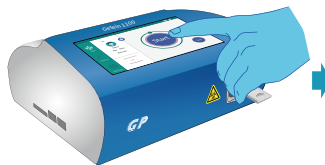
Quick mode (mass samples rapid test mode)



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
NEW 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 ₂ -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





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



KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#100/07-2021

Wir / We

TECO Medical Instruments Production and Trading GmbH

Name des Herstellers / Manufacturer's name
Dieselstrasse 1, 84088 Neufahrn, Germany
Anschrift / Address

erklären in alleiniger Verantwortung, dass die unten gelisteten IVD Zubehör Produkte:
declare under our own responsibility, that the IVD accessories products, listed below:

Doppelküvette / <i>Double cuvette</i>	Ref. 19 000 02
Einzelküvette / <i>Single cuvette</i>	Ref. 20 000 02, 24 100 00
4-fach Küvette / <i>Cuvette 4 pos/ea</i>	Ref. 80 521 10
6-fach Küvette / <i>Cuvette 6 pos/ea</i>	Ref. 80 560 00
6-fach Küvette (micro) / <i>Cuvette 6 pos/ea (micro)</i>	Ref. 80 570 00

allen anwendbaren Anforderungen folgender Richtlinien entsprechen: *meet all applicable requirements of:*

1. Richtlinie 98/79/EG über In-vitro Diagnostika und ihrem Zubehör, klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"- im Sinne von Zubehör zu In vitro Diagnostika gemäß Artikel 1.

1. Directive 98/79/EC on In-vitro diagnostic medical devices and their accessories, classified according to article 9 as: "all other products" – and in term of accessories for in vitro diagnostics according to article 1.

2. Richtlinie 2011/65/EU (RoHS III)

2. Directive 2011/65/EU (RoHS III)

Das QM-System des Herstellers ist zertifiziert nach:

The QM-system of the manufacturer is certified for:

EN ISO 13485:2016

EN ISO 13485:2016

Konformitätsbewertungsverfahren gemäß:

Conformity assessment procedure according to:

Gemäß Anhang III der Richtlinie 98/79/EG

According to Annex III of Directive 98/79/EC

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

Neufahrn, 27.07.2021
Neufahrn, July 27, 2021

Matthias Dieckmann
General Manager





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 Hötzi
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-APTT-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

TECO

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

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fax: +49-8773/707 80-29

Neufahrn, 26/04/2018

TO WHOM IT MAY CONCERN

We confirm that the instruments Coatron X Eco, Coatron X Pro and Coatron X Top have a closed cuvette system. Cuvettes have to be purchased with voucher identification code from TECO GmbH.



Christian Hoetzl
General Manager
TECO Germany

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 1st, 2023 to December 31st, 2024

Termination:

Confirmation ends automatically on Dec. 31st 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 18th, 2023

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl



CERTIFICATE OF TRAINING

Vitalie Goreacii

General manager of
Sanmedico
Chisinau
Republic of Moldava

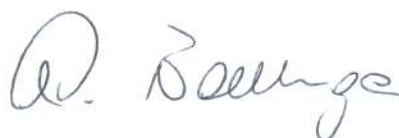
have participated with success at the training session supervised
by TECO GmbH, Germany for following instruments:

Coatron A series

- Installation
- Application
- General use, also in combination with TECAM
- Maintenance
- Troubleshooting
- After Sales Service

Training details:

Supervisor: Chr. Baumgartner, Director RD of TECO
Device: Coatron A4 + A6, Inhouse Master Device
Place: Laboratories of TECO
Date: May 5th 2023



Dipl.-Ing. Univ. (TUM)
Christian Baumgartner
Director R&D

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



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Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



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^{1,2}. 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 storage⁴

- 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% NaCl₂ 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%.⁵

**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



Calcium Chloride 0,025M

TECO

**IVD****REF****A0350-050, A0350-100**

Intended Use

This product is used in combination with reagent TEClot APTT-S (Cat.No. A0320) to determine the APTT or also for other 25mM CaCl₂ requiring coagulation tests.

Contents & Determinations

Product	Calcium Chloride	Calcium Chloride
Cat.No.	A0350-050	A0350-100
CaCl ₂ 0.025M	10x5 mL	10x10 mL

Determinations

Coatron M	2000 Det.	4000 Det.
Coatron A	1000 Det.	2000 Det.

Preparation

Ready to use.

Storage and Stability

Unopened reagents are stable until the expiration date shown on the label stored at 2-8°C.

Opened reagent is stable for 30 days at 2-8°C in the original vial.

Precautions

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.

Calcium Chloride Solution contains sodium azide. Sodium azide under acid conditions yields Hydrazoic acid, an extremely toxic compound. Azide compounds should be diluted with running water before being discarded. Upon disposal, azide compounds should be flushed with large volumes of water. These precautions are recommended to avoid deposits in metal pipes in which explosive conditions may develop.

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	IVD In Vitro Diagnostica	Biological hazard	REF Catalogue Number	Consult accompanying documents
Store at 2-8°C	CE EU conformity	Manufacturer	LOT Lot. Number	EC REF Authorized Representative





IVD

REF

A0350-050, A0350-100

Verwendungszweck

Wird zusammen mit dem Reagenz TEClot APTT-S (Kat. Nr. A0320) zur Bestimmung von der APTT verwendet oder auch für andere Gerinnungstests, für die 25mM CaCl₂ benötigt wird.

Inhalt und Bestimmungen

Produkt	Kalzium Chlorid	Kalzium Chlorid
Kat. Nr.	A0350-050	A0350-100
CaCl ₂ 0.025M	10x5 mL	10x10 mL

Bestimmungen

Coatron M	2000 Det.	4000 Det.
Coatron A	1000 Det.	2000 Det.

Vorbereitung

Das Reagenz ist gebrauchsfertig

Lagerung und Stabilität

Ungeöffnete Reagenzien sind bei einer Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum haltbar.

Geöffnete Reagenzien sind bei Lagerung zwischen 2-8°C im Originalfläschchen 30 Tage haltbar.

Vorsichtsmaßnahmen

Haut- und Augenkontakt vermeiden. Schutzkleidung tragen. Abfälle unter Beachtung der vorgeschriebenen internationalen, nationalen und lokalen Bestimmungen entsorgen.

Die Calcium Chlorid Lösung enthält Natriumazid. Unter sauren Bedingungen setzt Natriumazid Hydrogenazid frei, ein höchst giftiger Wirkstoff. Azidverbindungen sollten unter laufendem Wasser gelöst werden bevor sie entsorgt werden. Diese Vorsichtsmaßnahmen werden empfohlen, um Ablagerungen in Metallrohren zu verhindern, die explosive Bedingungen entwickeln könnten.

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

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.¹ Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use². 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

Coatlon M*	400 Det.	1000 Det.	800 Det.	2000 Det.
Coatlon A4	200 Det.	500 Det.	400 Det.	1000 Det.
Coatlon 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 storage³

- 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. Coatlon 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: Coatlon 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^{4,5}. 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 Coatlon 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 Clauss¹ entwickelten Methode verwendet. Der Fibrinogenpegel kann auf Grund von Entzündungen, Schwangerschaft und dem Gebrauch von Ovulationshemmern ansteigen². 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

Coatron M*	400 Det.	1000 Det.	800 Det.	2000 Det.
Coatron A4	200 Det.	500 Det.	400 Det.	1000 Det.
Coatron 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 12 days	15-25 °C 5 days	37 °C 24 Std
TEControl oder Plasma	2-8 °C 8 Std	15-25 °C 4 Std	-20 °C 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 Lagerung³

- Verfüßes 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: Coatron 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: Coatron 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^{4,5}. 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

Präzision:	VK% (Einzellauf)	VK% (Mehrfachlauf)
Normale Kontrolle	< 5,0	< 5,0
Abnormale Kontrolle	< 5,0	< 10,0

(Typische Leistung beim Gerät Coatron 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.





IVD

REF

A0501-010, A0501-025, A0511-020, A0511-050

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:	- Protokoll für A4+A6 - Stabilitätsdaten neu			
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^{1,2}.

The APTT reagent in the kit contains phospholipids and silica to ensure a highly consistent and stable product³. The APTT reagent is lupus anticoagulant insensitive. Lupus anticoagulant insensitive reagents yield more reliable factor assay results than reagents, which are sensitive to lupus inhibitors⁴.

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 storage⁵

- 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° 14d at -20°C 6m at -70°C

Procedure**A. Automated Method: Coatron A**

See application book of device

B. Manual Method: Coatron X

- Prewarm **CaCl₂** (0.025M) at 37°C for at least 10 min.
- Pipette **25 µL of sample** into a test cuvette. Prewarm at 37°C for 1-2 minutes.
- Add **25 µL APTT-S reagent** and incubate exactly for **3 min** at 37°C.
- Add **25 µL of CaCl₂** (0.025M) and simultaneously start test.
- 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 polypropylen tubes at -20°C is stable for 30 days

Limitations

- 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
- Laboratory Techniques
 - Perform tests at 37°C.
 - Use only high purity water.
 - Optimum pH is 7.0-7.5.
- Interfering substances
 - Bilirubin 40mg/dL
 - 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

- 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).
- Triplett DA, Harms CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol* 70, 556-569 (1978).
- 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).
- Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis* 25, 98-105 (1995).
- 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.^{1,2}

Das APTT Reagenz in diesem Kit enthält Phospholipide und Silizium, um ein sehr widerstandsfähiges und stabiles Produkt zu gewährleisten³. Das Reagenz reagiert nicht auf Lupus Antikoagulanzen und liefert daher verlässlichere Ergebnisse bei Faktorbestimmungen⁴. 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 ⁵

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 silikonisiertem 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. Calciumchlorid (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 CaCl₂** (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. 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.

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**

Präzision:	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	358

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

