

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
 - Hemostasis Reagents Complete product line
- all instruments with complete accessory, consumables and spare parts

This document is signed in Neufahrn, Germany, on January 18th, 2023

TECO Medical Instruments Production+Trading GmbH


Christian Hoetzl



Certificate of Approval

This is to certify that the Management System of:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00038268

The scope of this approval is applicable to:

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



Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited



0001



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: **Neufahrn, 2022-08-31**
Place and date of issue:



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-APTTs-A0320-050AM
5	A0401-020	TEClot TT	10x2ml TT	Thrombin time / reptilase / batroxbin time	W0103020103 / 55988 B-TT-A0401-0207P
6	A0511-020	TEClot FIB	10x2ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-020N2
7	A0511-050	TEClot FIB	10x5ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-050NB
8	C1010-020	TEChrom AT	6x6ml reagent FXa 3x3 ml substrate	Antithrombin	W0103020602 / 56156 B-AT-C1010-020HL
9	D2010-012	Red D-Dimer	3x4ml latex 3x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2010-0126W
10	D2020-005	Blue D-Dimer LC	1x5ml latex LC 1x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2020-0057E
11	P8001-010	TECal N	10x1ml	Calibration plasma for haemostasis	W0103020701 / 45786 B-CAL-P8001-005X8
12	P8200-005	TECal DD	5x1ml	Calibration plasma for haemostasis	W0103020701 / 47348 B-CAL-P8200-005XX
13	P6001-010	TEControl N	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6001-010H7
14	P6101-010	TEControl A	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6101-010HQ
15	P6201-010	TEControl A Plus	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6201-010J9
16	P5001-010	TEClot Factor II	10x1ml	Coagulation factor ii (prothrombin)	W0103020202 / 30542 B-FAC-II-P5001-010ML
17	P5101-010	TEClot Factor V	10x1ml	Coagulation factor v	W0103020204 / 30544 B-FAC-V-P5101-010AN
18	P5201-010	TEClot Factor VII	10x1ml	Coagulation factor vii	W0103020205 / 30545 B-FAC-VII-P5201-0107B
19	P5301-010	TEClot Factor VIII	10x1ml	Coagulation factor viii	W0103020207 / 30547 B-FAC-VIII-P5301-01097
20	P5401-010	TEClot Factor IX	10x1ml	Coagulation factor ix	W0103020208 / 30548 B-FAC-IX-P5401-0106C
21	P5501-010	TEClot Factor X	10x1ml	Coagulation factor x	W0103020209 / 30549 B-FAC-X-P5501-010EQ
22	P5601-010	TEClot Factor XI	10x1ml	Coagulation factor xi	W0103020210 / 30551 B-FAC-XI-P5601-010A8
23	P5701-010	TEClot Factor XII	10x1ml	Coagulation factor xii	W0103020211 / 30552 B-FAC-XII-P5701-010CJ

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



KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#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



TECO

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

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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



Quality Management
We are certified
Voluntary participation in regular
monitoring according to ISO 9001:2008



TECO

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CERTIFICATE

for: **Mr. Vitalie Goreacii**

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

have participated with success at the intensive training session:

Application and technical training for following instruments:

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

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

Place of Training: **TECO – Germany**

Date: **November 18th, 2019**



Christian Hoetzi
General Manager



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

Coatron M**	200 Det.	800 Det.	2000 Det.
Coatron A4	100 Det.	400 Det.	1000 Det.
Coatron 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 Coatron 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: Coatron A**

Prothrombin Time		A4		A6				A4		A6	
PAT	Patient	50µl	CP1	25µl	CP1	Incubation	0s	SENS	2		
BUF	IBS Buffer	0µl	P39	0µl	P79	Maxtime	120s	POINTS	4		
CLR	-	0µl	-	0µl	-	Unit	251	MIX	No		
DP	-	0µl	P00	0µl	P00	Method	Coag	Clean	0	0	
R0	-	0µl	P00	0µl	P00	Math	log XY	Multi	1	3	
R1	-	0µl	P00	0µl	P00	CT-Mech	No	S-Corr	0%		
R2	PT Reagent	100µl	P25	50µl	P46	Deadtime	7s	T-Corr	30% - 4s		

B. Manual Method: Coatron 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.

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

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 Coatron 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.



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

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.

*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 Imdazole 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. Coatron A**

Fibrinogen		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	
RO	-	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: Coatron M

- 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

- Pipette **50 µl diluted standard or patient plasma** (1:10) into a test cuvette. Prewarm at 37°C for 1-2 minutes.

- 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 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.

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 Coatron 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	TEClot FIB
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

	400 Def.	1000 Def.	800 Def.	2000 Def.
Coatron M*				
Coatron A4	200 Def.	500 Def.	400 Def.	1000 Def.
Coatron A6	200 Def.	500 Def.	400 Def.	1000 Def.

*Mikromethode (75µL insgesamt)

- Thrombin Reagenz:
Enthält Rinderthrombin (~80 NIH) mit Stabilisatoren.
REF: A0501-010/A0511-020: mit 2ml hochreinem Wasser anlösen
REF: A0501-025/A0511-050: mit 5ml hochreinem Wasser anlösen
- IBS Puffer: gebrauchsfertig, 125ml
Enthält gepufferte Natriumchlorid Lösung, pH 7,3-7,4
- TECal Normal: Mit 1ml hochreinem Wasser anlösen
Enthält mit Zitrat versetztes menschliches Plasma.
- TEControl A: Mit 1ml hochreinem Wasser anlösen
Enthält mit Zitrat versetztes menschliches Plasma.

Nach der Anlösung vorsichtig leicht schwenken und bei Raumtemperatur 15 Minuten stehen lassen. Vor Gebrauch gut mischen. Nicht schütteln.

Lagerung und Stabilität

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

Thrombin Reagenz*	2-8 °C	15-25 °C	37 °C
	12 days	5 days	24 Std
TEControl oder Plasma	2-8 °C	15-25 °C	-20 °C
	8 Std	4 Std	30 Std

* Reagenz muss vor UV-Licht und Verdunstung geschützt werden.

Vorsichtsmaßnahme

Haut- & Augenkontakt vermeiden. Abfälle gemäß lokaler Richtlinien für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös behandelt werden.

Probenentnahme und Lagerung³

- Venöses 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	
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

- 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
- Labortechniken
 - Tests bei 37°C durchführen
 - nur hochreines Wasser verwenden
 - der optimale pH Wert ist 7,0-7,5

Leistungsdaten

Präzision:	VK% (Einzelauf)	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.
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- 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:	<ul style="list-style-type: none"> - 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) Wertermittlung 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



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 Verkäuflichkeit 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

24 100 00 Single Cuvettes - 500

24 200 00 Single Cuvettes - 5000



Information of use

The Cuvette as general laboratory article is suitable to hold a reaction mixture for use in optical analyzers which are used in laboratories for in vitro diagnostic tests.

The cuvettes are ready for immediate use. They have unlimited shelf life if stored at 0 - 50°C.

Content

Product	Single Cuvettes	Single Cuvettes
Cat.No.	24 100 00	24 200 00
Content	500 pcs (500 det.)	5000 pcs (5000 det.)

The Cuvettes can be used with Coatron X Analyzers.

For application with semi-automated Coagulation System Coatron X, each box contains a voucher label with a VIN and PIN code to generate a ticket on the web-based registration page (www.teco-reg.com).

The ticket information (VIN/PIN) must be entered for the respective device to release the number of tests for this device only. The (VIN/PIN) can only be used once per unit.

Precautions and waste information

The Cuvette should only be used once in analyzers. To prevent contamination (sample/reagent), it is advised to avoid contact with skin and eyes. Suitable protective clothing and gloves are recommended.

Please also note the disposal of components in accordance with local regulations for infectious material.



Material: pure, clear Polystyrol (PS)
 Maximum volume should be less than ~ 500µL
 Minimum volume: 75 µL
 Dimensions max.: Ø11,5 mm x 24 mm

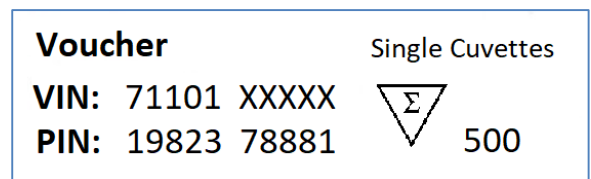
24 100 00

Example Picture of the package – 500 Single Cuvettes



Packaging:

1. Log Bag, Dim.: (mm) 165 x 295 x 0,05, Mat.: LDPE;
2. Card Box, Dim.: (mm) 252 x 104 x 65
3. Paper Sleeve with Identification and Information



Example of Voucher – 500 Single Cuvettes/Pack

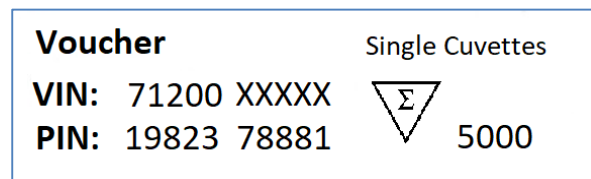
24 200 00

Example Picture of the package – 5000 Single Cuvettes



Packaging:

1. Log Bag, Dim.: (mm) 600 x 400 x 0,05, Mat.: LDPE;
2. Card Box, Dim.: (mm) 400 x 250 x 150
3. Label with Identification and Information



Example of Voucher – 5000 Single Cuvettes/Pack

Gebrauchsinformation

Die Küvette als allgemeiner Laborartikel eignet sich zur Aufnahme eines Reaktionsgemisches zur Verwendung in optischen Analysegeräten, welche in Laboren für in-vitro-diagnostische Tests verwendet werden.

Die Küvetten sind sofort einsatzbereit. Sie sind unbegrenzt haltbar, wenn sie bei 0 - 50°C gelagert werden.

Inhalt

Produkt	Einzelküvette	Einzelküvette
Kat. Nr.	24 100 00	24 200 00
Inhalt (Stck.)	500 (500 Tests)	5000 (5000 Tests)

Die Küvetten können mit dem halb-automatischen Coagulations System Coatron X verwendet werden.

Dazu enthält jede Packung ein Voucher-Etikett mit einem VIN- und PIN-Code, um ein Ticket auf der webbasierten Registrierungsseite zu generieren (www.teco-reg.com).

Die Ticketinformationen (VIN/PIN) müssen für das jeweilige Gerät eingegeben werden, um die Anzahl der Tests für dieses Gerät freizugeben. Die (VIN/PIN) kann nur einmal pro Einheit verwendet werden.

Vorsichtsmaßnahmen und Entsorgungshinweise

Die Küvette sollte nur einmal im Analysegerät verwendet werden. Um eine Kontamination (Probe/Reagenz) zu vermeiden, ist es ratsam, den Kontakt mit Haut und Augen zu vermeiden. Es werden geeignete Schutzkleidung und Handschuhe empfohlen.

Bitte beachten Sie auch die Entsorgung der Komponenten in Übereinstimmung mit den örtlichen Vorschriften für infektiöses Material.



Material: klares Polystyrol (PS)
 maximales Volumen: nicht über ~ 500µL
 minimales Volumen: : 75 µL
 max. Abmessungen: Ø11,5 mm x 24 mm

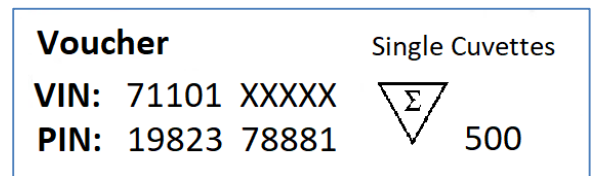
24 100 00

Beispielbild – Packung mit 500 Einzelküvetten



Verpackung:

1. Beutel, Maße: (mm) 165 x 295 x 0,05, Mat.: LDPE;
2. Karton, Maße: (mm) 252 x 104 x 65
3. Papierhülle mit Beschreibung und Informationen



Beispiel des Voucher – 500 Einzelküvetten/Pack

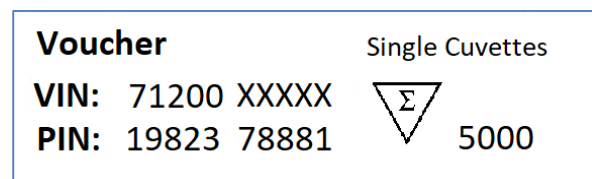
24 200 00

Beispielbild – Packung mit 5000 Einzelküvetten



Verpackung:

1. Beutel, Maße: (mm) 600 x 400 x 0,05, Mat.: LDPE;
2. Karton, Maße: (mm) 400 x 250 x 150
3. Label mit Artikelbeschreibung und Informationen



Beispiel des Voucher – 5000 Einzelküvetten/Pack