



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 Hötzl
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



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



Zertifikat

Hiermit wird bescheinigt, dass das Managementsystem von:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Deutschland

durch LRQA geprüft und bewertet wurde und den folgenden Normen entspricht:

ISO 13485:2016

Gültigkeits-Nr.: ISO 13485 – 00038268

Das Managementsystem ist anwendbar für:

Konstruktion, Entwicklung, Herstellung, Lagerung und Vertrieb von Gerinnungsmessgeräten und in-vitro Diagnostik Reagenzien aus den Bereichen der Hämostaseologie und Koagulation.



Paul Graaf

Area Operations Manager, Europe

Ausgestellt von: LRQA Limited



0001



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.



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

Calcium Chloride 0,025M

TECO

**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 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	IVD In-Vitro Diagnostik	Biologische Gefahr	REF Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	CE EU Konformität	Hersteller	LOT Lot. - Nummer	EC REP Bevollmächtigter





IVD

REF

A0401-020

Intended Use

TEClot TT reagent can be used manually or on semi-automated and automated instruments. The test is commonly applied to detect various sources of interference with normal blood coagulation. Prolongation of the thrombin clotting time can be taken as a qualitative indication of abnormal fibrinogen levels (high or low), or the presence of interfering substances such as FDP's or heparin. Quantitative evaluation of the possible causes of prolonged thrombin clotting time should be performed as follow-up studies, such as APTT or chromogenic assay for heparin, Clauss fibrinogen, FDP determinations, heparin neutralization by protamine sulphate or polybrene¹, normal plasma mixing studies² or reptilase assay³ to distinguish between hypofibrinogenaemia and FDP effects.

Contents & Determinations

Product	TEClot TT
Cat.No.	A0401-020
TT Reagent*	10 x 2mL

Determinations

Coatron M	Coatron A4	Coatron A6
800	400	800

*Each vial contains a lyophilized preparation of 26 units bovine thrombin with buffers and stabilizers. The final thrombin concentration in test application for Coatron systems is 4.33 E/mL.

Preparation

Reconstitute the reagent with 2 mL purified water. Allow to stand for 5 minutes then mix gently by inversion.

Storage & Stability

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

	-20 °C	12 °C	20-25 °C
TT Reagent	1 month	24 hours	8 hours

The vials can be only frozen once.

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 and 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/ μ L)
- 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**

TT A0401-020	A4		A6			A4	A6		A4	A6
PAT Patient	100 μ l	CP1	50 μ l	CP1	Incubation	0s	SENS	2		
BUF -	0 μ l	P00	0 μ l	P00	Maxtime	120s	POINTS	-		
CLR -	0 μ l	-	0 μ l	-	Unit	3	MIX	No		
DP -	0 μ l	P00	0 μ l	P00	Method	Coag	Clean	0	2	
R0 -	0 μ l	P00	0 μ l	P00	Math	-	Multi	1	3	
R1 -	0 μ l	P00	0 μ l	P00	CT-Mech	No	S-Corr	0%		
R2 TT Reagent	50 μ l	P27	25 μ l	P50	Deadtime	5s	T-Corr	20% - 3s		

(Refer to instrument operation manual for detailed instructions)

B. Manual Method: Coatron M system

- Pipette **50 μ l of sample** into a test cuvette. Incubate at 37°C for 1-2 minutes.
- Add **25 μ l of TEClot TT** reagent 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 normal results are 12 – 24 s⁶. 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 μ l stored in closed polypropylen 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
- Heparin below 1U/mL will not interfere results.

B. Laboratory Techniques

- Perform tests at 37°C.
- Use only high purity water.
- Optimum pH is 7.0-7.5.

As well as the cause of elongated Thrombin Clotting Times indicated above, a recent report has suggested that many systemic amyloidosis patients with bleeding complications may have a circulating inhibitor which prolongs the Thrombin Clotting Time⁵. Also therapeutic levels of heparin may entirely abolish clotting in the Thrombin Clotting Time test, although neutralization with protamine sulphate or polybrene should correct the Thrombin Clotting Time¹.

Performance Characteristics

Precision:	CV% (within run)	CV% (inter-runs)
Normal control	< 3.0	< 5.0
Abnormal control	< 3.0	< 5.0

(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

- Laposata et al. The Clinical Haemostasis Handbook, Yearbook Medical Publishers Inc., p219, 1989.
- Thompson, A.R. and Harker, L.A. Manual of Haemostasis and Thrombosis. 3rd Ed., F.A. Davis Co., p62, 1983.
- DeMott, W.R., in: Laboratory Test Handbook, 2nd Ed., Jacobs D.S. et al Eds., LexiComp Inc., p432-433, 1990.
- NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays
- Gastineau, D.A. et al. Inhibitor of the Thrombin Time in Systemic Amyloidosis: A Common Coagulation Abnormality Blood, 1991, 77: 2637-2640.
- Lothar Thomas, Labor und Diagnose, 6.Auflage, 2005, Page 846

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





IVD

REF

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

Intended Use

The TEClot FIB is intended for the quantitative determination of fibrinogen in human plasma according to method developed by Clauss.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 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. 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

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 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 Zentrifugation 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	IVD	In-Vitro Diagnostik	Biologische Gefahr	REF	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	CE	EU Konformität	Hersteller	LOT	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.
- 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:	<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.			





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



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 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



IVD

REF

D2020-005, D2020-010

Intended Use

Immunoturbidimetric reagent for the quantitative determination of D-Dimer concentration in human plasma on optical coagulometers at 400-470nm.

Background

At wound healing blood clots will be broken down by the process of fibrinolysis. Thereby, fibrin degradation products (FDP) such as D-Dimer (DD) occur in the plasma. Elevated level are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC)^{1,2}. High D-dimer levels during pregnancy are associated with complications³. Because of the high sensitivity negative results can be used to exclude DVT or PE. However imaging tests (like ultrasonic) must be applied for diagnosis of DVT or PE

Contents & Determinations

Product	Blue D-Dimer LC Kit-65	Blue D-Dimer LC Kit-130
Cat.No.	D2020-005	D2020-010
Latex	1x5 mL	2x5 mL
Reaction Buffer	1x7 mL	2x7 mL
Sample Dilution Buffer	1x7 mL	1x7 mL
TECal DD	1x1 mL	1x1 mL
TEControl N	1x1 mL	1x1 mL
TEControl A	1x1 mL	1x1 mL

Determinations

Coatron M	65 Det.	130 Det.
Coatron A4	65 Det.	130 Det.
Coatron A6	110 Det.	220 Det.

Preparation

Latex: liquid, ready to use

Contains micro particle coated with monoclonal antibodies MA-8D3 suspended in a buffer solution containing stabilizers detergent and preservatives. Agitate the latex by repeatedly the vial after storage. Allow the latex to equilibrate at the working temperature of the instrument for 30 min before use.

Reaction Buffer: liquid, ready to use. Contains stabilizers detergent and preservatives.

Sample Dilution Buffer: Saline Solution, Ready to use

TECal & TEControl: dried, contains lyophilized human plasma enriched for D-dimer, reconstitute with 1 mL distilled water.

Storage & Stability

Unopened reagents and controls loose about 1% activity per month and should be used within expiration date and stored at 2-8°C. Opened reagent:

	2-8 °C	20-25 °C	37°C	Aliquot
Latex & Buffer	4 weeks	8 hours	8 hours	6m at 2-8°C
TECal & TEControl	24 hours	8 hours	2 hours	30d at -20°C

Split D-Dimer reagent into aliquots of two or more vials (siliconised glass) immediately, if longer stability is required after opening. Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions

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

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part sodium citrate (3.2% or 3.8%) and mix well
3. Centrifuge the specimen at 1500g for 15 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 8 hours, otherwise store frozen and thaw just prior to use.

Procedure

A. Automated Method

Blue DD LC D2020-xxx		A4		A6				A4		A6	
PAT	Patient	25µL	CP2	15µL	CP3	Incubation	60s	SENS	0		
BUF	Sample Diluent	0µL	P39	0µL	P79	Maxtime	180s	POINTS	2		
CLR	-	0µL	-	0µL	-	Unit	30721	MIX	No		
DP	-	0µL	P00	0µL	P00	Method	Imun	Clean	1	3	
R0	-	0µL	P00	0µL	P00	Math	Lin	Multi	0	0	
R1	Reaction Buffer	50µL	P37	30µL	P52	CT-Mech	No	S-Corr	0%		
R2	Latex Reagent	75µL	P38	45µL	P53	Deadtime	21s	T-Corr	0%		

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

B. Manual Method

System setup	OD-Corr	Coag.-Corr
Coatron M1 (400nm) Firmware C1.20	180	120
Coatron M2 (400nm) Firmware C1.15	0%	0%
Coatron M4 (400nm) Firmware C1.11b	0%	0%

1. Pipette 25 µL plasma to cuvette(s).
2. Add 50 µL Reaction Buffer.
3. Incubate for 2 – 10 min.
4. Add 75 µL prewarmed Latex and mix at least "15x" with pipette. (Avoid air bubbles during mixing and do not touch cuvette, if double cuvettes are used.)

Calibration

A calibration must be performed every 3 month. Make dilutions of TECal DD with sample dilution buffer. Refer to the table below.

	Concentration	Sample	Sample diluent
Cal. 1	~ 3000 ng/mL	200 µL TECal DD	-
Cal. 2	~ 1500 ng/mL	200 µL TECal DD	200 µL
Cal. 3*	1 ng/mL	-	-

* This point is not measured, but just the zero point entered as 1ng=1mE

Expected Results

Results below CUT-OFF value can be regarded as D-dimer negative and are typical for normal healthy normal subjects. Elevated levels are observed in causes of PE, DVT (deep venous thrombosis) or DIC or trauma.

D-Dimer results can be reported in D-dimer units (DDU) or Fibrinogen Equivalent Units (FEU). 1 FEU is equal to 1.74 DDU. Teco is using DDU in certificates.

Quality Control

TEControl or other commercial DD control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). Ensure that calibration data are not older than 3 months.

Limitations

Great care must be taken to minimize variations which may occur by seemingly insignificant factors.

Laboratory Techniques and Requirement

1. Appropriate mixing of cuvette after test start is required.
2. Don't touch cuvette during measurement - single cuvettes may useful.
3. Very bright external UV light sources like sunlight will interfere result

Interferences

1. Bilirubin: No affect below < 0.1g/L
2. Hemoglobin: No affect below < 4.0g/L
3. Heparin: No affect
4. Lipids: No affect below < 2.5g/L. Samples above 5.0g/L will give false low DD results and must diluted and repeated.

Performance Characteristics

The quantification limit is 150ng/mL (DDU). Results below should considered as "<150". Samples > 5000ng/mL should be re-assayed 1:4 diluted with Saline Solution.

Precision:	Appropriate mixing is required to achieve good accuracy.
TEControl A	CV. <8% (within run)
TEControl N	CV. <10% (within run)

Performance:

CUT-OFF	Sensitivity	Specifity	NPV	PPV
DDU=200ng/mL	97%	62%	99%	41%

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

1. Elms, M.J. et al. Rapid detection of cross-linked fibrin degradation products in plasma using monoclonal antibody-coated latex particles. J. of Clin. Path. 85:360-364, 1986.
2. Declercq, P. et al. Fibrinolytic response and fibrin fragment D-dimer levels in patients with deep vein thrombosis. Thrombosis and Haemostasis 58:1024-1029, 1987.
3. Ballegeer, V. et al. Fibrinolytic response to venous occlusion and fibrin fragment D-dimer levels in normal and complicated pregnancy. Thrombosis and Haemostasis 58:1030-1032, 1987.
4. 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.





Verwendungszweck

Immunturbidimetrisches Reagenz zur quantitativen Bestimmung der D-Dimer Konzentration in menschlichem Plasma auf photometrischen Koagulometer bei 400-470nm.

Hintergrund

Während der Wundheilung werden Blutgerinnsel durch den Prozess der Fibrinolyse abgebaut. Dabei entstehen Fibrinolyseprodukte (FSP) wie D-Dimer (DD). Erhöhte Werte werden bei klinischen Zuständen wie tiefer Venenthrombose (TVT), Pulmonalembolie (PE) und disseminierter intravasaler Koagulation (DIC)^{1,2} beobachtet. D-Dimer-Werte erhöhen sich während einer Schwangerschaft und hohe Werte deuten auf Komplikationen³ hin. Aufgrund der hohen Sensitivität können negative Laborergebnisse zur Ausschlussdiagnostik für TVT oder PE verwendet werden. Für die Krankheitsbestätigung müssen bildgebende Verfahren (z.B. Ultraschall) angewandt werden.

Inhalt & Bestimmungen

Produkt	Blue D-Dimer LC Kit-65	Blue D-Dimer LC Kit-130
Artikelnummer	D2020-005	D2020-010
Latex	1x5 mL	2x5 mL
Reaktionspuffer	1x7 mL	2x7 mL
Verdünnungspuffer	1x7 mL	1x7 mL
TECal DD	1x1 mL	1x1 mL
TEControl N	1x1 mL	1x1 mL
TEControl A	1x1 mL	1x1 mL

Bestimmungen

Coatron M	65 Det.	130 Det.
Coatron A4	65 Det.	130 Det.
Coatron A6	110 Det.	220 Det.

Vorbereitung

Latex: flüssig, gebrauchsfertig. Enthält mit monoklonalen Antikörpern MA-8D3 überzogene Mikropartikel, gelöst in einer Pufferlösung mit Stabilisatoren, Reiniger und Konservierungsmittel. Latex nach Lagerung mehrmals schütteln. Lassen Sie das Latex vor Gebrauch 30 Minuten auf Geräteatemperatur aufwärmen.

Reaktionspuffer: flüssig, gebrauchsfertig. Enthält Stabilisatoren, Reiniger und Konservierungsstoffe

Verdünnungspuffer: Kochsalzlösung, gebrauchsfertig

TECal & TEControl: getrocknet, enthält lyophilisiertes Humanplasma, angereichert für D-Dimer, mit 1ml destilliertem Wasser anlösen.

Lagerung und Stabilität

Ungeöffnete Reagenzien und Kontrollen verlieren ca. 1% Aktivität pro Monat, sollten bei 2-8°C gelagert und innerhalb des Verfallsdatums verbraucht werden.

Geöffnete Reagenzien:

	2-8 °C	20-25 °C	37°C	Teilmengen
Latex & Puffer	4 Wochen	8 Stunden	8 Stunden	6m bei 2-8°C
TECal & TEControl	24 Stunden	8 Stunden	2 Stunden	30d bei -20°C

Gelöstes Plasma kann nur einmal und in Teilmengen (120-150µL) eingefroren werden. Bei -20°C in geschlossenen Polypropylenröhrchen gelagert, müssen die Teilmengen innerhalb 30 Tagen verbraucht werden.

Vorsichtsmaßnahmen

Kontakt mit Haut und Augen vermeiden. Geeignete Schutzkleidung tragen. Abfälle unter Beachtung der örtlichen Bestimmungen für infektiöses Material entsorgen. Alle Bestandteile wurden auf HIV, BHV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut als potentiell infektiös angesehen werden.

Probensammlung und Lagerung⁴

- Unter sauberen Bedingungen venöses Blut mittels Venenpunktur entnehmen
- Sofort 9 Teile Blut mit einem Teil Natriumzitrat (3.2% oder 3.8%) mischen
- Proben bei 1500g für 15 Minuten zentrifugieren (Thrombozyten < 10000/µL)
- Plasma nach dem Zentrifugieren entfernen und in einem Röhrchen aus Kunststoff oder silikonisiertem Glas lagern
- Plasma innerhalb 8 Stunden verwenden; andernfalls tiefgekühlt lagern und unmittelbar vor Gebrauch auftauen

Vorgehensweise

A. Automatenmethode:

Blue DD LC D2020-xxx		A4		A6				A4		A6	
PAT	Patient	25µL	CP2	15µL	CP3	Incubation		60s	SENS		0
BUF	Sample Diluent	0µL	P39	0µL	P79	Maxtime		180s	POINTS		2
CLR	-	0µL	-	0µL	-	Unit		30721	MIX		No
DP	-	0µL	P00	0µL	P00	Method		Imun	Clean	1	3
RO	-	0µL	P00	0µL	P00	Math		Lin	Multi	0	0
R1	Reaction Buffer	50µL	P37	30µL	P52	CT-Mech		No	S-Corr		0%
R2	Latex Reagent	75µL	P38	45µL	P53	Deadtime		21s	T-Corr		0%

Erklärung der Symbole:

Verfallsdatum	In Vitro Diagnostik	Biolog. Gefahr	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	EU Konformität	Hersteller	Lot. Nummer	Bevollmächtigter

B. Manuelle Methode: Coatron M Series

System setup	OD-Corr	Coag.-Corr
Coatron M1 (400nm) Firmware C1.20	180	120
Coatron M2 (400nm) Firmware C1.15	0%	0%
Coatron M4 (400nm) Firmware C1.11b	0%	0%

- 25 µL Plasma in eine Testküvette(n) pipettieren
- 50 µL Reaktionspuffer hinzufügen
- 2-10 Minuten erwärmen
- 75 µL vorgewärmtes Latex hinzufügen und mindestens "15x" mit der Pipette mischen. (Luftblasen vermeiden. Keine Doppelküvetten verwenden oder Proben einzeln messen).

Kalibrierung

Alle 3 Monate muss eine Kalibrierung durchgeführt werden. Verdünnungen von TECal DD mit Verdünnungspuffer herstellen wie in der untenstehenden Tabelle beschrieben:

	Konzentration	Probe	Verdünnungspuffer
Cal. 1	~ 3000 ng/mL	200 µL TECal DD	-
Cal. 2	~ 1500 ng/mL	200 µL TECal DD	200 µL
Cal. 3*	1 ng/mL	-	-

* Dieser Punkt wird nicht gemessen, es wird lediglich der Nullpunkt als 1ng=1mL eingegeben

Erwartete Ergebnisse

Ergebnisse unterhalb des CUT-OFF werden als D-Dimer negative bewertet und sind typisch für normalgesunde Menschen. Hohe Werte können ein Hinweis auf PE, TVT, DIC oder Trauma sein. Die Ergebnisse können in D-Dimer Einheiten (DDU) oder Fibrinogen äquivalenten Einheiten (FEU) angegeben werden. 1 FEU entspricht dabei 1.74 DDU. TECO verwendet DDU in allen Zertifikaten.

Qualitätskontrolle

Es wird empfohlen, TEControl oder anderes handelsübliches DD Kontrollplasma in regelmäßigen Abständen zu testen um konstante Testergebnisse zu gewährleisten. Die Kalibrierdaten sollten nicht älter als 3 Monate sein.

Einschränkungen

Es muss sorgfältig darauf geachtet werden, Schwankungen durch scheinbar unwesentliche Faktoren zu minimieren.

A. Labortechniken

- Angemessenes Vermischen der Küvette nach dem Start ist erforderlich.
- Küvetten während der Messung nicht berühren
- Sehr intensive äußerliche UV-Lichtquellen (z.B. Sonnenlicht) können das Ergebnis beeinflussen

B. Interferenzen

- Bilirubin: Kein Effekt unter < 0.1g/L
- Hemoglobin: Kein Effekt unter < 4.0g/L
- Heparin: Kein Effekt
- Lipids: Kein Effekt unter < 2.5g/L. Ab 5.0g/L werden falsch niedrige D-Dimer Werte gemessen. In diesem Fall muss die Probe verdünnt und wiederholt werden.

Leistungscharakteristik

Die Mengenbeschränkung liegt bei 150ng/mL (DDU). Ergebnisse darunter sollen als „<150“ betrachtet werden. Proben > 5000ng/mL sollten, 1:4 mit Kochsalzlösung verdünnt, erneut angesetzt werden.

Genauigkeit:	Richtiges Mischen ist erforderlich um Genauigkeit zu erreichen
TEControl A	CV. <8% (während des Programms)
TEControl N	CV. <10% (während des Programms)

Leistung:

CUT-OFF	Sensitivität	Spezifität	NPV	PPV
DDU=200ng/mL	97%	62%	99%	41%

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

- Elms, M.J. et al. Rapid detection of cross-linked fibrin degradation products in plasma using monoclonal antibody-coated latex particles. J. of Clin. Path. 35:360-364, 1986.
- Declercq, P. et al. Fibrinolytic response and fibrin fragment D-dimer levels in patients with deep vein thrombosis. Thrombosis and Haemostasis 58:1024-1029, 1987.
- Ballegeer, V. et al. Fibrinolytic response to venous occlusion and fibrin fragment D-dimer levels in normal and complicated pregnancy. Thrombosis and Haemostasis 58:1030-1032, 1987.
- 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.





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	35

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 Antikoagulant 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 10Minuten lang zentrifugieren (Thrombozyten <10000/µl)
4. Plasma nach der Zentrifugierung entfernen und in einem Röhrchen aus Plastik oder silikonisiertes Glas aufbewahren.
5. Plasma innerhalb von 4 Stunden verwenden, andernfalls gefroren lagern und kurz vor Gebrauch auftauen.

Stabilität von Plasma: 4h bei 18-26°C 8h bei 2-8° 14d bei -20°C 6m bei -70°C

Verfahren**A. Automatenmethode: Coatron A**

Siehe Applikationsbuch des Gerätes

B. Manuelle Methode: Coatron X

1. 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 Antikoagulant vermeiden
3. Kontaminierung mit Gewebethromboplastin vermeiden
4. falsches Verhältnis von Antikoagulant 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	35

Heparin (U/mL)	0 U/mL	0,2 U/mL	0,4 U/mL
APTT Gerinnungszeit	35	70	180

Diese Werte sollen nur als Richtlinien verwendet werden. Jedes Labor sollte mit eigenen Instrumenten und Techniken Sensitivitätswerte erstellen.

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußerlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Referenzen

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol* 36, 212-219 (1961).
2. Triplett DA, Hams CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol* 70, 556-569 (1978).
3. Stevenson KJ, Easton AC, Thomson JM, Poller L. The reliability of activated partial thromboplastin time methods and the relationship to lipid composition and ultrastructure. *Thromb Haemost* 55, 250-258 (1986).
4. Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis* 25, 98-105 (1995).
5. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays

Erklärung der Symbole:



Verfallsdatum



In-Vitro Diagnostik



Biologische Gefahr



Katalog-Nummer



Begleitpapiere beachten





IVD

REF

P6001-010

Intended Use

Use as a normal control for following coagulation tests:

**PT, APTT, Thrombin time, Fibrinogen,
Anti-thrombin and D-Dimer**

Contents

10 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation

Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B): Reconstitute individual vials with **1,7 ml** distilled water.

Storage & Stability

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

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C
1 month	8 hours	4 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions

This product contains substance from human origin!
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Expected Results

Refer to "Certificate of Analysis".

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





P6001-010

Verwendungszweck

Als normale Kontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit, Fibrinogen,
Antiithrombin und D-Dimer**

Inhalt

10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung

Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TEClot PT-B): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

Lagerung und Stabilität

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

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C
1 Monat	8 Stunden	4 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

Vorsichtsmaßnahmen

Dieses Produkt enthält Substanzen humanen Ursprungs! Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

Erwartete Ergebnisse

Lesen Sie das Analysenzertifikat

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die 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





IVD

REF

P6101-010

Intended Use

Use as an abnormal control for following coagulation tests:

**PT, APTT, Thrombin time, Fibrinogen,
Antithrombin and D-Dimer**

Contents

10 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation

Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B): Reconstitute individual vials with **1,7 ml** distilled water.

Storage & Stability

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

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C
1 month	8 hours	4 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions

This product contains substance from human origin!
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Expected Results

Refer to "Certificate of Analysis".

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





IVD

REF

P6101-010

Verwendungszweck

Als abnormale Kontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit, Fibrinogen,
Antithrombin und D-Dimer**

Inhalt

10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung

Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TEClot PT-B): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

Lagerung und Stabilität

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

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C
1 Monat	8 Stunden	4 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

Vorsichtsmaßnahmen

Dieses Produkt enthält Substanzen humanen Ursprungs! Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

Erwartete Ergebnisse

Lesen Sie das Analysenzertifikat

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die 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





IVD

REF

P8001-005

Intended Use

Use as a calibrator or normal control for following coagulation tests:

**PT, APTT, Thrombin time, Fibrinogen,
Factors: II, V, VII, VIII, IX, X, XI, XII,
Antithrombin, Protein-C, free Protein-S,
D-Dimer**

Contents

5 x 1 mL freeze dried citrate-anticoagulated human plasma

Preparation

Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TECLOT PT-B CAT=A0260 xxx): Reconstitute individual vials with **1,7 ml** distilled water.

Storage & Stability

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

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C	37°C
30 days	24h	8h	2 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions: Potential Biohazardous material

This product contains substance from human origin! Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Performance Characteristics:

Refer to "Certificate of Analysis".

Limitations:

The control plasma is subject to the limitations of the assay system (reagent + instrument). Results out of expected range may indicate deterioration, false test calibration or problems with one or more components of the test system

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

P8001-005

Verwendungszweck

Als Kalibrator oder Normalkontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit, Fibrinogen,
Faktoren: II, V, VII, VIII, IX, X, XI, XII,
Antithrombin, Protein-C, freies Protein-S,
D-Dimer**

Inhalt

5 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung

Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TEClot PT-B CAT=A0260 xxx): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

Lagerung und Stabilität

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

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C	37°C
30 Tage	24 Stunden	8 Stunden	2 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

Vorsichtsmaßnahmen: Potentiell infektiöses Material

Dieses Produkt enthält Substanzen humanen Ursprungs! Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

Erwartete Ergebnisse

Lesen Sie das Analysenzertifikat

Einschränkungen:

Das Kontrollplasma unterliegt den Einschränkungen der verwendeten Reagenzien und Geräte. Ergebnisse außerhalb des Sollbereichs können verursacht werden durch abgelaufene Materiale, ungültige Methodenkalibration oder Problemen an Reagenz, Gerät oder Zubehör.

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußerlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

Verfallsdatum	In-Vitro Diagnostik	Biologische Gefahr	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	EU Konformität	Hersteller	Lot. - Nummer	Bevollmächtigter





IVD

REF

P8001-010

Intended Use

Use as a calibrator or normal control for following coagulation tests:

**PT, APTT, Thrombin time, Fibrinogen,
Factors: II, V, VII, VIII, IX, X, XI, XII,
Antithrombin, Protein-C, Protein-S**

Contents

10 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation

Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B): Reconstitute individual vials with **1,7 ml** distilled water.

Storage & Stability

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

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C	37°C
30 days	24h	8h	2 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions

This product contains substance from human origin!
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Expected Results

Refer to "Certificate of Analysis".

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	In Vitro Diagnostica	Biological hazard	Catalogue Number	Consult accompanying documents
Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative



IVD

REF

P8001-010

Verwendungszweck

Als Kalibrator oder Normalkontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit, Fibrinogen,
Faktoren: II, V, VII, VIII, IX, X, XI, XII,
Antithrombin, Protein-C, Protein-S**

Inhalt

10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung

Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TEClot PT-B): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

Lagerung und Stabilität

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

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C	37°C
30 Tage	24 Stunden	8 Stunden	2 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

Vorsichtsmaßnahmen

Dieses Produkt enthält Substanzen humanen Ursprungs! Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

Erwartete Ergebnisse

Lesen Sie das Analysenzertifikat

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Veräußlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

Verfallsdatum	In-Vitro Diagnostik	Biologische Gefahr	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	EU Konformität	Hersteller	Lot.- Nummer	Bevollmächtigter

CE Declaration of Conformity

We,
Atlas Medical GmbH
 Head office: Ludwig-Erhard-Ring 3
 15827 Blankenefelde-Mahlow Germany
 Tel: +49(0)33708355030
 Email: info@atlas-site.com

Middle East Site: : Sahab Industrial Zone Area, King Abdullah II Industrial City
 Amman 11512, Jordan
 Tel.: +962 6 4026468
 Fax: +962 6 4022588
 Email: info@atlas-medical.com

Declare our responsibility that the following product:

Blood Grouping Reagents:
 (Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent , Anti-AB Monoclonal Reagent and
 Anti-D IgG/IgG blend Reagent)
 see the attached list of variants

That are classified as Annex II, list A

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate and
 complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016
 EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,
 EN 13612:2002, EN 13641:2002 , EN 13975:2003,
 EN ISO 13485:2016, EN 62366-1:2020

And

Intended for In-Vitro Professional use only.

Conformity Assessment Route:

Annex IV.3 –Approval full Quality Assurance System.

Annex IV.4-EC Design Examination (of the product)

Notified Body:

G-MED	CE	0459
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GMED, Laboratoire national de métrologie et d'essais

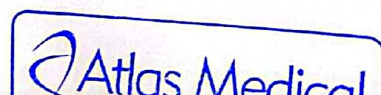
1 rue Gaston Boissier 75015 Paris

Tél. : 01 40 43 37 00 , TVA:FR 28 839 022 522

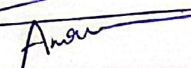
EC Certificates No.:

- CE Certificate of Approval full Quality Assurance System: 33540 rev4.
- CE Certificate Of EC Design Examination: 33544 rev3.

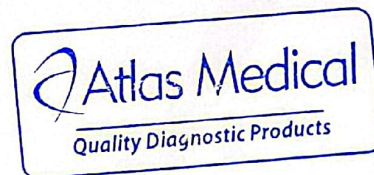
Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09 th october 2017	26 th May 2025	Amani Al-habahbeh (RA Manager)		

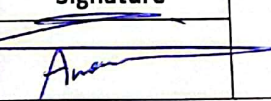


Product Code	Product Name	GMDN Code
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/Carton Box	52532
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 10 vials / Plastic Pack	52532
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 18 vials / Carton Box	52532
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, / Carton Box	52538
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials / Plastic Pack	52538
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials / Carton Box	52538
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/ Carton Box	46442
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack	46442
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/Carton Box	46442
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 1 vial/ Carton Box	52647
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 10 vials / Plastic Pack	52647
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 18 vials / Carton Box	52647
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1 Vial/Carton Box	52532
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials / Plastic Pack	52532
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	52538
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials /Plastic Pack	52538
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)),3x10ml / plastic Pack	45308
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml /Plastic Pack	52695
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	46442
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,10 vials /Plastic Pack	46442
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,18 vials / Carton Box	45308
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 1Vial/ Carton Box	52647
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 10 vials / Plastic Pack	52647

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature.	MRXDO10F.11 21.10.2013
	09 th october 2017	26 th May 2025	Amani Al-habahbeh (RA Manager)		

8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128)),3x10ml/Plastic Pack	45308
8.02.47.1.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Carton Box.	45308
8.02.47.3.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Plastic Pack	45308
8.02.47.5.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/128)), 3x10ml/Plastic Pack	45308
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64)), 4x10ml/Carton Box	45308
8.02.49.2.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/128)), 4 x 10ml, 4 vials/Plastic Pack	45308
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml/Plastic Pack	45308
8.02.53.1.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml, 4vials/Plastic Pack	45308
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box	52532
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1/1024) , 10 ml/vial ,1Vial/ Carton Box	52538
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1/1024) , 10 ml/vial , 1Vial/ Carton Box	45308
8.02.85.0.0010	Anti-D IgG/IgM Blend Reagent , Titer 1/256, 10ml/vial, 1Vial/ Carton Box	52647



Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09 th october 2017	26 th May 2025	Amani Al-habahbeh (RA Manager)		

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

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

pour les activités
for the activities

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

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

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

Voir addendum

See addendum

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

ISO 13485: 2016

Début de validité / Effective date October 9th, 2023 (included)

Valable jusqu'au / Expiry date : October 8th, 2026 (included)

Etabli le / Issued on : October 9th, 2023

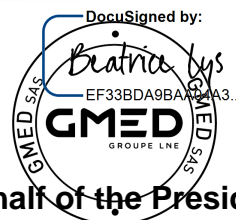


**CERTIFICATION
DE SYSTEMES
DE MANAGEMENT**
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36655-2

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

Renouvelle le certificat 36655-1



On behalf of the President
Béatrice LYS
Technical Director

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

French version :

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

English version:

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

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

French version:

Siège social, responsable de la mise sur le marché

English version:

Headquarter, legal manufacturer

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


French version:

Conception, fabrication et contrôle final

English version:

Design, manufacture and final control

2 sites / 2 sites

DocuSigned by:
Beatrice Lys
FF33BDA88AA04A3...


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

Date: 05/Jan/2023

STATEMENT


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

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

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: 

Date: 05.01.2023

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Blood Grouping Reagents:

Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants SLIDE AND TUBE TESTS

IVD For In-Vitro and professional use only

2°C  8°C Store at 2- 8°C

INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemagglutination using slide or tube test techniques in whole blood samples or anticoagulant blood samples collected in EDTA, citrate or heparin tubes.

INTRODUCTION & PRINCIPLES

Blood grouping reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are diluted with phosphate buffer containing sodium chloride, EDTA and bovine albumin to give reagents that are optimized for use in tube and slide procedures. **Anti-A monoclonal reagent is colored with acid blue (patent blue) dye, Anti-B monoclonal reagent is colored with acid yellow (tartrazine) dye, and Anti-AB monoclonal reagent is not colored.** The test procedure is based on hemagglutination principle, where red cells possessing the antigen agglutinate in the presence of the corresponding antibody indicating that the result is positive. The test is considered negative when no agglutination appears.

Anti-D IgG/IgM blend reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D IgG/IgM blend reagent is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^{VI}) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D^{VI} and low grade weak D (D^{VI}) phenotypes by the indirect anti-globulin techniques.

Anti-D IgG/IgM blend reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D IgG/IgM blend reagent is not colored. The procedure is based on hemagglutination principle, where red cells' possessing the antigen agglutinates in the presence of the corresponding antibody in the reagent indicating that the result is positive. The test is considered negative when no agglutination appears.

MATERIALS

MATERIALS PROVIDED

Blood Grouping Reagents:

- Anti-A monoclonal reagent (10 ml/vial), Clone: (9113D10).
- Anti-B monoclonal reagent (10 ml/vial), Clone: (9621A8).
- Anti-AB monoclonal reagent (10ml/vial), Clone: (152D12+9113D10).
- Anti-D IgG/IgM Blend reagent (10 ml/vial), Clone: (P3X61 + P3X21223B10 + P3X290 + P3X35).

MATERIALS NEEDED BUT NOT PROVIDED

- Plastic test tube or glass.
- Isotonic saline solution (% 0.9) NaCl).
- Applicator sticks.
- Centrifuge (100-1200 (g) for tube test).
- Timer.
- Incubator
- Anti-Human Globulin Reagent (can be ordered from Atlas Medical).
- White or transparent glass slide.

PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- The test is for well trained professional healthy user not for lay user.
- These reagents are derived from animal and human sources, thus, appropriate care must be taken in the use and disposal of these reagents, as there are no known test methods that can guarantee absence of infectious agents.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.
- Protective clothing should be worn when handling the reagents.
- **The reagents contain (0.1-0.2%) Sodium Azide and 0.02% sodium arseniate which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.**
- The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
- Avoid cross contamination of reagents or specimens.
- Visible signs of microbial growth in any reagent may indicate degradation and the use of such reagent should be discontinued.

- Don't use these reagents if the label is not available or damaged.
- Do not use dark glass slide.
- Don't use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.
- Hemolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well lit area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so don't drink or eat beside it.
- If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 - 8°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

REAGENT PREPARATION

- The reagents are intended for use as supplied, no prior preparation or dilution of the reagent is required.
- All reagents should be brought to room temperature before use.

SPECIMEN COLLECTION AND PREPARATION

- Blood collected with or without anticoagulant (EDTA, Heparin or Citrate) can be used for Antigen typing.

Note: Blood collected without anticoagulant should be tested immediately.

- The specimens should be tested as soon as possible after collection. If testing is delayed, the specimens should be stored at 2- 8 °C. Sample must be retained to room temperature prior to analysis. (Testing should be carried out within five days of collections).
- Insure that there is no sign of hemolysis.
- At the time of the test, centrifuge the blood sample at 1200 RCF for 3 minutes.
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

1. Prepare a 5% suspension of red blood cells in isotonic solution.
2. Using the vial dropper, transfer a drop (40±10µl) of each reagent into a separate and appropriately marked tube.
3. Add 50 µl of red blood cell suspension prepared in step 1.
4. Shake to homogenize the mixture, then centrifuge at 500g for **1 minute**.
5. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
6. Read the reaction immediately.
7. For Anti-D tube, if the reaction is weak or negative, shake the tubes and incubate at 37°C for **15 minutes**.
8. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
9. Add one drop (50µl) of the AHG reagent into the tube. Mix and centrifuge at 120g for **1 minute**.
10. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
11. Read the reaction immediately.

B. ANTIGLOBULIN INDIRECT METHOD for ANTI-D

1. After immediately centrifuging and reading as above, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
2. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
3. Add one drop (40 µl ± 10 µl) of ANTI-HUMAN GLOBULIN to the tube. Mix and centrifuge at 120 (g) for **1 minute**.
4. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
5. Read the reaction immediately.

C. DIRECT SLIDE METHOD AT ROOM TEMPERATURE

1. Bring reagents and samples to room temperature (18-25°C).
2. Using the wax pen divide the slide into appropriate numbers of divisions.
3. Using the provided dropper, place one drop (40 µl ± 10 µl) of each reagent onto its correspondent division on the slide.
4. Add 25µl of the precipitated cells next to each drop of reagents.
5. Mix the reagent and the cells using a clean stirring stick over an area with a diameter of approximately 20-40mm.
6. Incubate the slide at room temperature (18-25°C) without stirring for **30 seconds**.
7. Hold the slide and gently rock the slide for **3 minutes** and observe macroscopically for any agglutination.
8. Read the reaction immediately.

READING THE RESULT

POSITIVE: If Agglutination appears.

NEGATIVE: If no agglutination is observed.

Use the below table to determine the blood group:

Result of each reaction				ABO Group
Anti-A monoclonal reagent	Anti-B monoclonal reagent	Anti-AB monoclonal reagent	Anti-D IgG/IgM blend reagent	
+	-	+	+	A+
+	-	+	-	A-
-	+	+	+	B+
-	+	+	-	B-
+	+	+	+	AB+
+	+	+	-	AB-
-	-	-	+	O+
-	-	-	-	O-

STABILITY OF THE REACTIONS

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Slide tests should be interpreted within three minutes to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of reagents.
- Delay in reading and interpreting results may result in weekly positive or falsely negative reactions. Slide tests should be interpreted at the end of the three minutes.

PROCEDURE LIMITATION

- False positive/ negative results may occur due to:
 - Contamination from test materials.
 - Improper storage, cells concentration, incubation time or temperature.
 - Improper or excessive centrifugation.
 - Deviation from the recommended technique.
 - Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions when tested using slide test method. It is advisable to re-test weak subgroups using tube test method.
- Weaker reactions may be observed with stored blood than with fresh blood.
- ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
- ABO blood grouping interpretation on individuals greater than 6 months old should be confirmed by testing serum or plasma of the individual against group A and group B red cells (reverse grouping). If the results obtained with the serum do not correlate with the red cell test, further investigation is required.
- Return the kit to the agent if it does not function properly.
- Anti-D IgG/IgM blend Reagent tests conducted on particular weak-D phenotypes, while satisfactory, cannot ensure recognition of all weak variants, due to the variability of antigen patterns.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The following tables compare the results in slide and tube techniques of 3 lots of Atlas Medical reagents and the results of a CE marked device.

Slide Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
232	232	232	232	100%
Tube Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
212	212	212	212	100%

Slide Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				

CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%
Tube Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%

Slide Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
241	241	241	241	100%
Tube Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
243	243	243	243	100%

Slide Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
33	33	33	33	100%
Tube Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
24	24	24	24	100%

No inversion in diagnosis has been shown: from a qualitative point of view we have observed 100% compliance in direct group testing in slide and tube techniques for determination of A, B, AB and O groups for the three lots of Atlas Medical.

QUALITY CONTROL

The reactivity of all blood grouping reagents should be confirmed by testing known positive and negative red blood cells on each day of use. To confirm the specificity and sensitivity, Blood grouping reagents should be tested with antigen-positive and antigen-negative red blood cells.

REFERENCES

1. BCSH Blood Transfusion Task Force. Guidelines for microplate techniques in liquid-phase blood grouping and antibody screening. Clin. Lab. Haem 1990; 12, 437-460.
2. Issitt P. D. Applied Blood Group Serology, 3rd ed. Miami: Montgomery Scientific, 1985.
3. Kholer G., Milstein C. Continuous culture of fused cells secreting antibody of predefined specificity, 256, 495-497, 1975
4. Messeter L. et. al. Mouse monoclonal antibodies with anti-A, anti-B and anti-A,B specificities, some superior to human polyclonal ABO reagents, Vox Sang 46, 185-194, 1984
5. Race R.R. and Sanger R. Blood groups in man, 6th ed., Oxford: Blackwell Scientific, 1975.
6. Voak D. ET. al., Monoclonal anti-A and anti-B development as cost effective reagents. Med. Lab. Sci 39, 109-122. 1982.

7. Standards for Blood Banks and Transfusion Service. 11th Ed., Washington D.C., AABB 1984:25.

8. Widmann F.K.ed Technical Manual, 9th Ed., Washington D.C.: AABB 1985:9.



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LIST OF VARIANTS:

Product Code	Product Name
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/Carton Box
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, / Carton Box
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/ Carton Box
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials/Plastic Pack
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials/Carton Box
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 1 vial/ Carton Box
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 10 vials / Plastic Pack
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 18 vials / Carton Box
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1 Vial/Carton Box
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials / Plastic Pack
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials /Plastic Pack
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1 /256), Anti-D (1/64)),3x10ml / plastic Pack
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1 /256), 2x10ml/Plastic Pack
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,10 vials /Plastic Pack
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,18 vials / Carton Box
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 1Vial/ Carton Box
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 10 vials / Plastic Pack
8.02.47.0.0030	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-D (1 /128)),3x10ml/Plastic Pack
8.02.47.1.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Carton Box.
8.02.47.3.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Plastic Pack
8.02.47.5.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /128)), 3x10ml/Plastic Pack
8.02.49.0.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /64)), 4x10ml/Carton Box
8.02.49.2.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /128)), 4 x 10ml, 4 vials/Plastic Pack
8.02.53.0.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml/Plastic Pack
8.02.53.1.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml, 4vials/Plastic Pack
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial ,1Vial/ Carton Box
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial , 1Vial/ Carton Box
8.02.85.0.0010	Anti-D IgG/IgM Blend reagent (Titer 1 /256), 10ml/vial, 1Vial/ Carton Box

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