TECO
MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH
Dieselstraße 1
D-84088 Neufahrn N.B.
fon: +49-8773/707 80-0
fax: +49-8773/707 80-29

**TO WHOM IT MAY CONCERN**
To any governmental departments,
registration and/or trade offices in MOLDOVA

**Distribution Authorisation Letter**

This letter confirms that **Sanmedico**
**Mun. Chisinau**
**Str. Petricani 88/1 of. 10**
**Republica MOLDOVA**

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

**Sanmedico** will provide the following information to TECO GmbH when so required in relation to its market surveillance activities:
Reporting of incidents to TECO must take place within 3 working days
Serial number of the device, exact location of the device and the user.

Validity: January 1st, 2025 to December 31st, 2026

Termination: Confirmation ends automatically on Dec. 31st of 2026 and must be then renewed.

Products:

- Coatron M1 Semi-automated 1-channel Coagulometer (out of production)
- Coatron M2 Semi-automated 2-channel Coagulometer (out of production)
- Coatron X Eco Semi-automated 1-channel Coagulometer
- Coatron X Pro Semi-automated 2-channel Coagulometer
- Coatron X Top Semi-automated 4-channel Coagulometer
- Coatron A4 Fully automated Coagulometer, 4 optic channels
- Coatron A6 Fully automated Coagulometer, 6 optic channels
- Coatron A6 plus Fully automated Coagulometer, 6 optic channels

all instruments with complete accessory, consumables and spare parts

- Hemostasis Reagents Complete product line

This document is signed in Neufahrn, Germany, on Decamber 3th, 2024

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl
General Management

Medical Instruments TECO Production+Trading GmbH

Digitally signed by Dolgopol Iulian
Date: 2025.02.12 11:04:18 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Current issue date: 10 November 2022
Expiry date: 9 November 2025
Certificate identity number: 10479697

Original approval(s):
ISO 13485 - 10 November 2022

# Certificate of Approval

This is to certify that the Management System of:

## TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

**ISO 13485:2016**

Approval number(s): ISO 13485 – 00038268

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

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

**Paul Graaf**

Area Operations Manager, Europe

Issued by: LRQA Limited

UKAS MANAGEMENT SYSTEMS 0001

ISO 9001:2008 DEKRA Certification DEKRA Certified

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

Quality Management EN ISO 13485 DEKRA Certified

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# CERTIFICATE

for: **Mr. Vitalie Goreacii**

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

have participated with success at the intensive training session:

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

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

Supervisors: Mr. Chr. Hoetzl and Mrs. Wendy Guo

Place of Training: TECO – Germany

Date: November 18th, 2019

Christian Hoetzl
General Manager

TECO

CE

# KONFORMITÄTSERKLÄRUNG
# DECLARATION OF CONFORMITY

Doc#001-01/06-2022

Hersteller / Manufacturer: **TECO Medical Instruments Production and Trading GmbH**

Adresse / Address: **Dieselstrasse 1, 84088 Neufahrn, Germany**

Marktakteur / Actor ID SRN: **DE-MF-000022642** https://ec.europa.eu

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

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

**BASIS UDI-DI 426018278CMX81152**

IVD - halb-automatische Blutgerinnungsmessgeräte - Handelsbezeichnung, Typ, Kat.-Nr.
IVD - semi-automated Coagulation Systems - trade name, type, model, Cat.-No.

## Coatron X Eco / Coatron X Pro / Coatron X Top

**81 101 10** **81 101 20** **81 101 40**

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

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

**Verordnung (EU) 2017/746**
für in-vitro Diagnostika-IVDR
und dem harmonisierten Standard am 2022-05-12:

Risikoklassifizierung gemäß Artikel 47–Anhang VIII
**Regel 5 b – „Klasse A "**

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

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

EN ISO 18113-3:2011
DIN EN 62304:2018
DIN EN 62366-1
DIN EN 62366-1:2017
DIN EN 61326-1:2013
DIN EN 55011:2009 + A1:2010
IEC 61010-1:2010, AMD1:2016
IEC 61010-2-101:2015
IEC 61010-1:2010

Richtlinie 2011/65/EU RoHS III
(incl. (EU) 2015/863) - DIN EN IEC 63000

QM-System gemäß (EU) 2017/746 Art.10(8)
angewandter Standard: EN ISO 13485:2021

**Regulation (EU) 2017/746**
for In-vitro diagnostic medical devices
and it's harmonized standard at 2022-05-12:

Risk classified according to article 47 annex VIII
**Rule 5 b – "Class A"**

Conformity assessment procedure in accordance with:
(EU) 2017/746 Article 17 (annex II+III)

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

EN ISO 18113-3:2011
DIN EN 62304:2018
DIN EN 62366-1
DIN EN 62366-1:2017
DIN EN 61326-1:2013
DIN EN 55011:2009 + A1:2010
IEC 61010-1:2010, AMD1:2016
IEC 61010-2-101:2015
IEC 61010-1:2010

Directive 2011/65/EU RoHS III
(incl. (EU) 2015/863 - DIN EN IEC 63000

QM-Systems in accordance with (EU) 2017/746 art.10(8)
Applied standard procedure: EN ISO 13485:2021

Ort und Datum der Unterzeichnung:
Place and date of issue: Neufahrn, 2022-06-21

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC

Certificate -Bescheinigung

TECO
**Medical Instruments**
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**Dieselstrasse 1**
**D-84088 Neufahrn/NB**
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# CERTIFICATE OF TRAINING

**Vitalie Goreacii**
General manager of
Sanmedico
Chisinau
Republic of Moldava

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

**Coatron A series**

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

Training details:

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

TECO
Dipl.-Ing. Univ.
Christian Baumgartner

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

TOP
INNOVATION
2017 - 2018

Clotting
Chromogenic
Immunturbidimetric

# Coatron X

## Semi-automated
## Coagulation Analyzer Series

**With 1, 2 or 4 optical channels**


TECO
Innovation in Coagulation

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

The Coatron X instrument line is a consequent continuation in the development of the Coatron product line. Over 25 years in experience and innovation is the reference for our new Coatron X instrumentation line.
The unique detection principle in combination with the high-level analytical algorithm calculates exact, precise and reproducible results.
Easy in operation – self instructing user dialogue - reliable

**Highest optical resolution, enlarged optic range, smallest sample and reagent volume**
0.1 mOD, 0 - 3800 mOD, just with 75 µL sample and reagent volume
**Complete optical analysis**
No further parts required, like balls, stirrers etc.
**Adaptation of the light level**
Automatic light level adjustment of the optic channels to each sample
**Exclusion of disturbance**
Stray light reduction, exact temperature control, all parameter are preset

TECO

Innovation in Coagulation

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

**Coatron X - product family**


With 1, 2 or 4 optical channels.

www.teco-medical.com

Coatron X

# Prepared for the daily routine and the upcoming requirements

**One instrument – many possibilities**

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

MADE IN GERMANY

**Quality is our basic demand**

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

TECO CLOUD

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

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


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

DEKRA DEKRA

CE IVD

Coatron X

# The details make the difference

**Coatron X**

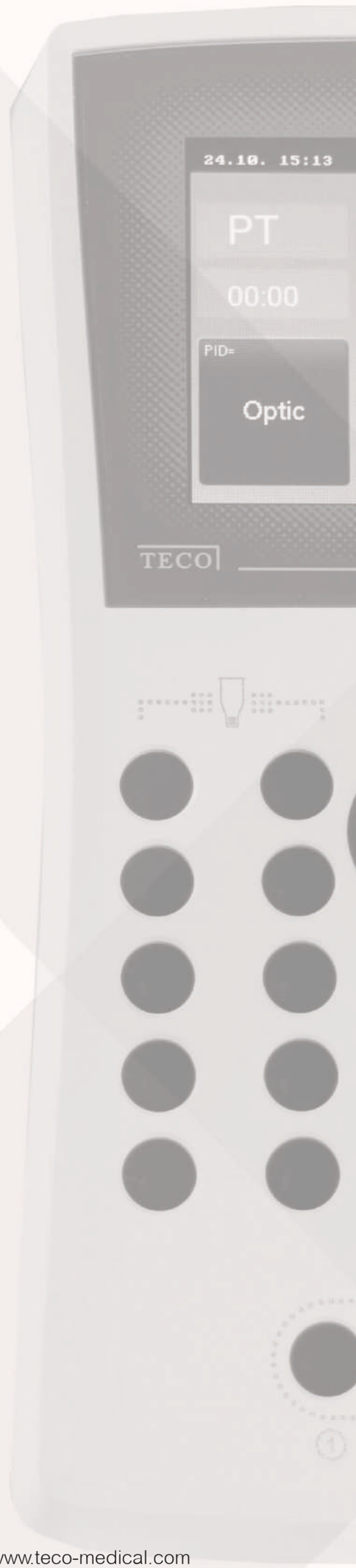
The remarkable details in every single component is achieved by selecting of premium suppliers.

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

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

**Software and connection possibilities**

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




# Operation details

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


**Intuitive operation and control**

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

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


**For small and mediate laboratory requirements**

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

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

**Interfaces**

**RS232 (2x)**

- For external serial printer and external barcodereader

**LIS/USB**

**Bluetooth**


Integrated barcode scan for reagents.

TECO CLOUD

**TECO Cloud Services**

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

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

For trading partners worldwide, please visit our web-page

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TECO
Innovation in Coagulation

CoatronX-E-v0E

# User Manual

# Coatron X Series

## Eco / Pro / Top


CE

Instructions intended for instruments
REF 8110110|8110120|8110140
Basis UDI-DI 426018278CMX81152

IVD

EN ISO 15223-1 EN ISO 18113-3

For In-Vitro Diagnostic use

**Versions**

| User manual | Instrument Software |
|---|---|
| 1 | 1.01.42 (first release) |
| 2 | 1.01.43 |
| 3 (minor correction on OPM) | 1.01.43 |
| 4 | 1.01.44 |
| 5 | 1.01.47 + 1.02.48 |
| 6 | 1.03.49 |
| 7 | 1.03.50 |
| 8 | 1.03.51 and higher |

**Copyright**



**Trademarks**

**Coatron** is a trademark of TECO Medical Instruments, Production + Trading GmbH. Other product names used in this User Manual are trademarks of the respective companies.

**Manufacturer**

Instrument is produced by
TECO Medical Instruments, Production + Trading GmbH
Dieselstrasse. 1
D-84088 Neufahrn, Germany
shortened for simplicity to **TECO GmbH**
Phone: +49 (0)8773 70780-0
Fax: +49 (0)8773 70780-29
Email: info@teco-gmbh.com
Internet: http://www.teco-gmbh.com

**Warranty**

The Coatron X Coagulometer is warranted for a period of one year after delivery or first installation unless agreed in written for a different period of warranty. It covers any defects in material, functionality or workmanship. For first installation the device must be registered online via www.teco-reg.com
(- see chapter 2.9 page 21 - “Registration”)

The warranty expires in case of failures caused by

- Accident, neglect of maintenance & service, abuse or misuse.
- Using unauthorized reagents, consumables or spare parts
- Unauthorized service. Any repair or service must be performed by authorized persons.

List of figures

# 1. INTRODUCTION

This device left the factory in fault-free certified condition regarding its safety and engineering functionality. To maintain this condition and ensure risk-free operation, the operator must comply with the safety warnings and information in this User Manual. (see Chapter 1.5 page 14 – “Safety information”)

***Use the Coatron X only in compliance with the instructions in this User Manual. Otherwise, the manufacturer shall exclude the liability for any damages to the Coatron X, patients or operators.***

## 1.1 SYMBOLS

The following standard symbols are used in this manual:

| Symbol | Meaning | Explanation |
|---|---|---|
| Courier | **Info** | Key on keypad. |
| CAPS | **Info** | Screen message. |
|  | **Read** | Indicates important information and tips. |
| ⇨ | **Info** | Describes reaction of **Coatron X** to operator input. |
|  | **Warning** | Risk of possible health damage or considerable damage to equipment, if warning is not heeded. |
|  | **Danger** | Potential risk to operating personnel or equipment due to electric shock. |
|  | **Biohazard** | Equipment can be potentially infectious due to the samples and reagents used. |
|  | **Laser Radiation** | Avoid direct eye exposure |

## 1.2 VIEWS OF THE DEVICE


FIGURE 1: TOP VIEW

Home Screen

Coloured Touch Display

Complete area is prewarmed to 37°C

1 x Reagent position Ø24mm
1 x Reagent position Ø22mm
1 x Reagent position Ø22mm, stirred

2 x Reagent positions Ø13mm

20 x Cuvette incubation positions

4 x Cuvette measurement positions
(depends on ECO/PRO/TOP version)


FIGURE 2: REAR VIEW

| | |
|---|---|
| 5V: | Power in |
| PC: | LIS or PC |
| SERVICE: | Software update |
| PRINTER: | Serial printer |
| BARCODE: | Handheld barcode scanner |

FIGURE 3: SIDE VIEW

## 1.3 CONSUMABLES / FURTHER EQUIPMENT

Detailed informations are available with the product pricelist or Leaflet or website

| | | |
|---|---|---|
| Consumables, laboratory equipment | Cuvettes for Coatron X | Box of 500 or 5000 pieces including one Voucher ticket |
| | Reagent adapter ∅ 24,5 → 22,5 mm | Helps to place vials with different sizes on device |
| | Stirring magnets, P=4 | Required to mix PT reagent. (only on Coatron Pro and Top) |
| additional technical equipment | External QR barcode reader | To read 1D or QR code for Patient-ID, Reagent and Tickets |
| | Glass Protection Foil Kit | Safe display glas from scratches. Kit includes foil, clean tissues & remover tool |
| | Thermal printer 60mm (Optional) | Print test results, Calibration data or System information |
| | TECAM Smart Software (Optional) | Patient management, Reagent Calibration management, Monitoring, Research, Statistics, Mirror print function, LIS communication (ASTM-1394) |

## 1.4 INTENDED USE

IVD

The **Coatron X Family** is designed to carry out coagulometric tests such as PT, PTT, TT, fibrinogen, single factor tests, chromogenic and immunoturbidimetric tests (for instance Antithrombin, D-dimer etc.) on human citrated plasma. The instrument has to be used for the expected purposes and in perfect technical condition, by qualified personnel, in working conditions and maintenance operations as described in this document. It is designed for laboratory use or clinical environment and trained users. It is not intended for home use.

### 1.4.1 COMPARISON OF COATRON-X SERIES

The Coatron X Series includes three different versions called ECO, PRO, TOP

| Coatron X Series | **ECO** | **PRO** | **TOP** |
|---|---|---|---|
| |  |  |  |
| Reagent and Optic block | Prewarmed to 37°C | | |
| Cuvette prewarm | 10x | 20x | 20x |
| Reagent prewarm, 24mm | 1x | 1x | 1x |
| Reagent prewarm, 22mm | 2x | 2x | 2x |
| Microtubes prewarm | 2x | 2x | 2x |
| Reagent stirrer | No | 1x | 1x |
| Printer, RS232 | Yes | | |
| Barcode Scanner, RS232 | Yes, external handheld barcode scanner for 1D or QR labels to read patient-ID, reagent information or vouchers. | | |
| LIS, USB | Yes | | |
| Firmware Update, USB | Yes | | |

| Measurement | ECO | PRO | TOP |
|---|---|---|---|
| Optic channels | 1 | 2 | 4 |
| Optic wavelength | 620nm (RED) | 405nm (UV) | 405nm (UV) |
| Cuvette, total volume | Single, 75µL | Single, 75µL | Single, 75µL |
| Global Clotting Assays | PT+aPTT+Fib+TT | PT+aPTT+Fib+TT | PT+aPTT+Fib+TT |
| Special Clotting Assays | - | All factors PS, LA | All factors PS,LA |
| Chromogenic Assays | - | AT, PC,HEP | AT, PC,HEP,AF10, |
| Latex enhanced Assays | D-Dimer | D-Dimer Free PS | D-Dimer Free PS |
| Whole Blood Testing | Yes (PT INR+%) | No | No |
| Software features | | | |
| Reagent Dual LOT<br>manage two different lots for each test | No | Yes | Yes |
| Test Calibration<br>LOT, expiry and upto 5 points for each test | Yes | Yes | Yes |
| Reagent Barcode<br>Input LOT+Expiry or Positive LOT detection | Yes | Yes | Yes |
| Patient Barcode<br>Input patient ID by barcode scanner upto 16char | Yes | Yes | Yes |
| System Barcode<br>Input voucher tickets by barcode scanner directly from display of smart device | Yes | Yes | Yes |
| Result Database<br>save recent 180 results onboard | Yes | Yes | Yes |
| Double Determination<br>Run patient twice and display mean value | No | Yes | Yes |
| Stopwatch function<br>count up or down incubation time | 1x | 2x | 4x |
| Result Identification<br>Patient ID or sample ID or Auto ID | Yes | Yes | Yes |
| Real Time Clock | Yes | Yes | Yes |
| Change language<br>EN, ESP, ITA, FR, DE - further on option | Yes | Yes | Yes |
| Start test at reagent addition<br>No expensive starter pipette required | Yes | Yes | Yes |
| Visualize Reaction Curve<br>Tecmoni Software required | Yes | Yes | Yes |
| Link to LIS over USB or network/ASTM<br>TECAM SMART Software required | Yes | Yes | Yes |

## 1.4.2 TEST METHODS

Following test are provided to detect of the human coagulation system, which can be bleeding or thrombosis and the monitoring of anti-coagulation drugs like Heparin or Marcumar.

| Test | Name | Specimen | Method | Coatron X | | |
|---|---|---|---|---|---|---|
| | | | | Eco | Pro | Top |
| PTB | Prothrombin Time | blood | clot | Yes | No | No |
| PT | Prothrombin Time | plasma | clot | Yes | Yes | Yes |
| APTT | Activated Partial Thromboplastin Time | plasma | clot | Yes | Yes | Yes |
| FIB | Fibrinogen | plasma | clot | Yes | Yes | Yes |
| TT | Thrombin Time | plasma | clot | Yes | Yes | Yes |
| AT | Antithrombin | plasma | chromogen | No | Yes | Yes |
| DD | D-Dimer | plasma | immuno | Yes | Yes | Yes |
| Factors | Factors II, V, VII, VIII, IX, X, XI, XII | plasma | clot | No | Yes | Yes |
| HEP | Heparin (anti Xa) | plasma | chromogen | No | Yes | Yes |
| PC | Protein C | plasma | chromogen | No | Yes | Yes |
| PS | Protein S | plasma | clot | No | Yes | Yes |
| PSF | Free Protein-S | plasma | immuno | No | Yes | Yes |
| LA-S | Lupus Screen | plasma | clot | No | Yes | Yes |
| LA-C | Lupus Confirm | plasma | clot | No | Yes | Yes |

## 1.4.3 SPECIMEN COLLECTION

| | |
|---|---|
| Type: | Human citrated plasma |
| Collection: | Veinvein puncture, 1:10 mixed sodium citrate 3.2% (0.105M) |
| Centrifugation: | 10min at 1500g |
| Storage: | Max 4h after collection at room temperature |
| | |
| Bilirubin: | < 50mg/dl |
| Hemoglobin: | < 9000mg/l |
| Triglyceride: | < 2500g/l |

Intended specimen for PTB (Coatron X Eco)

| | |
|---|---|
| Type: | Capillary blood from puncture of finger or citrated whole blood |

**In case of differences to the boxinserts of the reagent, always follow the instructions on the box insert.**

## 1.4.4 PRINCIPLE OF MEASURMENT

The detection of plasma clotting is based on a photometric principle. No mechanical aids like mixing bars are required. Blood plasma is filled into a cuvette. Special reagents are added, which initiate the blood coagulation. The cuvette is transmitted by ultra violet light during the coagulation process. When the sample starts to clot a change of light absorbance is measured. The time from measurement start to change of light (turning point) is called clotting time and expressed in seconds [s].

The conversion of coagulation time into a specific test unit is one using a linear, hyperbolic, semi-logarithmic or double-logarithmic interpolation of the stored calibration points. The current mathematical model is printed out in "TEST SETUP." Values outside the calibration range are calculated by extrapolation and flagged as " * ".

| Unit | Info | Decimal places | Maximum value |
|---|---|---|---|
| s | seconds | 1 | - |
| % | activity | 1 | 250.0 |
| U | units | 0 | 29999 |
| INR | Int. ratio | 2 | 99.00 |
| R | ratio | 2 | 99.00 |
| NR | polish ratio | 0 | 250 |
| mg/dl | | 0 | 999 |
| g/l | | 2 | 99 |
| IE/ml | Int. Units | 2 | 99 |
| mg/l | | 2 | 999 |
| µg/ml | | 3 | 9.000 |
| ng/ml | | 0 | 27500 |
| µg/l | | 0 | 27500 |
| IU/mL | Int. Units | 2 | 99.00 |

R = clotting time / normal time
NR = 100 *(normal time/clotting time)
INR = Ratio $^{ISI}$ (International Normal Ratio)
IU/mL = IE/mL = International Units (1.00 IU/mL = 100 % activity)

### 1.4.5 CLOTTING METHOD (PT, APTT,..)

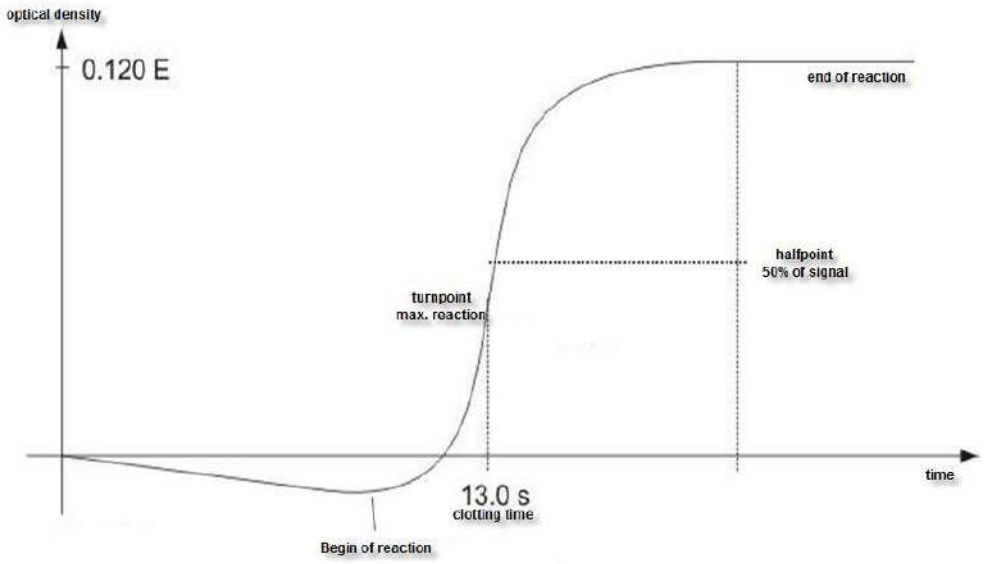



FIGURE 4: DETERMINATION OF TURNING POINT IN CLOTTING METHOD

The final reaction in the coagulation cascade is the transformation of fibrinogen into fibrin catalyzed by thrombin. Fibrin formation results in clouding (higher turbidimetric level) in the sample, which is measured by the photometer and stored as the extinction. The result in seconds is the time from the start of the reaction to the time of half rate of change (halfpoint).

### 1.4.6 CHROMOGENIC METHOD (ANTITHROMBIN):

The change of optical signal is not caused by clot reaction, but by the release of color particles (pNA) which causes a yellow color. The change of color is measured at 405nm and expressed as “dE/60sec” and proportional to the concentration or activity of analyte.

### 1.4.7 IMMUNTURBIDIMETRIC METHOD (D-DIMER):

The change of light is caused by Antigen – Antibody reactions, which scatter the light. The antibodies are linked to latex particles to amplify the optical reaction. The change of light is proportional to the concentration of antigen like D-Dimer and expressed as dE/120sec

## 1.5 SAFETY INFORMATION

No liability is assumed, if this product is not purchased from any other than the manufacturer or an authorized distributor.

**A. General use**

**A.1** This device must be installed at professional laboratories where a quality management system is established and good laboratory practice (GLP) is applied. The laboratory must follow local regulations about operating medical products.

**A.2** This device must be operated by a professional user only. It is not intended for point of care or home testing.

**A.3** Read user manual in its entirety prior first operation.

**A.4** Install device according to electrical and environmental conditions stated im chapter "Installation" of user manual.

**A.5** Operate the instrument as intended and instructed in the User Manual.

**A.6** Follow always product labeling and manufacturer's recommendations.

**A.7** Use only materials, consumables and (spare)parts such as reagent or cuvettes, which are intended or recommended for use on this instrument. Always contact manufacturer or local authorized distributor in case of doubts.

**A.8** Do not use materials after their expiry date or assigned shelf life.

**B. Laboratory use**

**B.1** Check correct function of instrument by performing quality control before running a series of patient samples or after test calibration.

**B.2** Do not operate the instrument after spilling reagent or liquids into the analyser. Contact local authorized distributor for servicing.

**B.3** Never use cuvettes more than once. Do not wash cuvettes. They are for single use only.

**C. Risk of infection**

**C.1** Consider all surfaces and materials, which might be in contact with plasma or other biological liquid as potentially infectious.

**C.2** Avoid direct contact with potential infectious materials or surfaces by wearing appropriate protective clothing.

**C.3** Follow the laboratory hygienic procedures during and after completion of work.

**D.** Maintenance and Service

**D.1** Only an authorized customer service may carry out any servicing.

**D.2** Decontaminate instrument before doing any servicing or shipment.

**D.3** Recycle instrument according to WEEE or local regulations for electronic equipment.

# 2. INSTALLATION OF THE **COATRON X**

## 2.1 SCOPE OF DELIVERY

Contents of standard delivery package:

- 1 Pc **Coatron X**
- 1 Pc Power Supply
- 200 Pcs Single cuvettes
- 5 Pcs Reagent container, Ø22,5mm
- 5 Pcs Reagent tubes, Ø11mm
- 1 Pc User Manual (not on picture below)
- 1 Pc Brochure with Safety Information (not on picture below)
- 1 Pc Display protection foil


FIGURE 5: STANDARD DELIVERY PACKAGE

## 2.2 CONDITIONS OF OPERATION

**Ambient conditions:**

| | |
|---|---|
| Operating Temperature | 15 to 30 °C |
| Humidity | < 70% rel. humidity |
| Elevation above NN sea level | < 3,000m |
| Free of dust | Grade 2 |
| Impact resistance | According to IEC/EN 61010-1, 8.2.2 |
| Not allowed | Vibrations, direct sun light and direct exposure to air condition. |

**Electrical conditions:**

100-240 VAC, 47 - 63Hz, no earthing required (Class-2)

**Electrostatic Discharge (ESD):**

No special requirements for ESD protection (shoes etc.)

**Storage conditions:**

0 - 50°C, max. 12 months in original package.

**Transport conditions:**

No special conditions required. The general regulations for transport can be used.

**Hygienic conditions:**

Validate your hygienic management system according to international applied Good Laboratory Practice (GLP) or similar quality standard. Any waste material must be considered as potentially infectious. Direct contact must be avoided. Protective gloves during operation, service or cleaning are required.

**Device environment:**

No special requirements. Instruments is suitable for or use in domestic and industrial establishments.

## 2.3 FIRST INSTALLATION

Inspect the packaging of the **Coatron X** and accessories for any visible external damage. If the packaging is damaged, contact the transport company so that any damage to the device or accessories can be assessed.

The instrument is ready to use and don't need a specific procedure.

**First installation procedure:**

1. Unpack and place instrument in conformity with conditions of operation (see previous chapter).
2. Install assessory (Protection foil, printer, barcode, Tecam – see next chapters)
3. Plug in power 5V.
4. Wait until green Status (approx. 15 min). The instrument is now ready to use.
5. Register instrument online for start of warranty period.
6. Activate 500 cuvettes (see chapter-5 "ticket system").

| | |
|---|---|
|  | *Keep the original packaging material for purposes of later transport* |

| | |
|---|---|
|  | maximum length of cables to external devices like printer, barcode or LIS must be less than 3m to keep compliance with EMC |

## 2.4 SWITCHING ON AND OFF

**Switching on**
Connect with power supply

***Important Information:***
The instrument requires about 15 minutes to heat up the optic block to 37°C. Afterwards it is ready for measurement, indicated by a green dot in the top right corner of the display. If the status symbol does not turn green, even after wating for 25 minutes, press the status symbol to see the device status to identify the problem.

**Switching off**
The device supports no power switch. It must be disconnected from power. To do this, unplug the power adapter from the socket on the device first and then disconnect the power supply.

**Standby**
The system switches to standby after 2 minutes of idle operation. In standby mode, the display brightness is reduced to save display life time and reduce power consumption. The next touch anywhere on the display disables the standby mode.

**Sleep**
Open menu and touch the “sleep” button: ⏻

The menu bar is displayed on top of screen and only available, if no measurement is ongoing. The power consumption during sleep is 0,2W.

**Wakeup**
To wake the device up from sleep, touch the display.


The system can be disconnected under any operation situations. There is no risk of system damage

## 2.5 DISPLAY PROTECTION FOIL

**Requirements**:

| | |
|---|---|
| Type: | Touchsensitive Protection foil, clean tissue wet and dry, Pick-off |
| Size: | same as Display (4,3”) |

**Installation:**

Ready to fix on display, as described in the Inlay
(clean display with clean tissues wet and dry and fix protection foil carefully)

## 2.6 EXTERNAL THERMAL PRINTER

**Requirements**:

| | |
|---|---|
| Type: | Serial RS232 Printer |
| Power: | external supply, 24V 1.5A |
| Cable: | 2 x Sub D9, female, straight, max length 3m |
| Interface: | RS232, 9600 Baud, 8, 1, No |

**Installation:**

The printer is ready to plug in. No settings are required.

Do not plug power supply of printer (24V) to Coatron-X. It will destroy the instrument! Double check before you plug-in.

## 2.7 EXTERNAL BARCODE SCANNER

**Requirements**:

| | |
|---|---|
| Type: | Serial handheld scanner |
| Power: | 5V DC over cable, PIN-9 |
| Cable: | Included to scanner |
| Interface: | RS232 9600 Baud, 8, 1, No |
| Setting: | No handshake or protocol. Barcode must be finished with carriage return. |

**Installation:**

The scanner is ready to plug in. no settings are required.

## 2.8 TECAM SMART

**Requirements**:

| | |
|---|---|
| License: | TECAM SMART fingerprint and activation code. |
| Cable: | USB, type A to B, max 3m |
| Interface: | USB |
| Setting: | no handshake or protocol. Barcode must be finished with carriage return. |

**Installation:**

a) Disconnect the device from PC.
b) Run setup.exe.
c) Confirm when asked to install Coatron X driver.
d) Connect device with PC.
e) Start TECAM

Further information available in chapter “7” or online help file of TECAM.

## 2.9 REGISTRATION

The instrument must be registered online for warranty or service issues

1) Open weblink www.teco-reg.com or scan QR Code →

2) Enter **SIN + PIN** of device

   Both can be seen on instrument license plate (Type label) or during startup or on info screen (touch green or red LED on home screen)

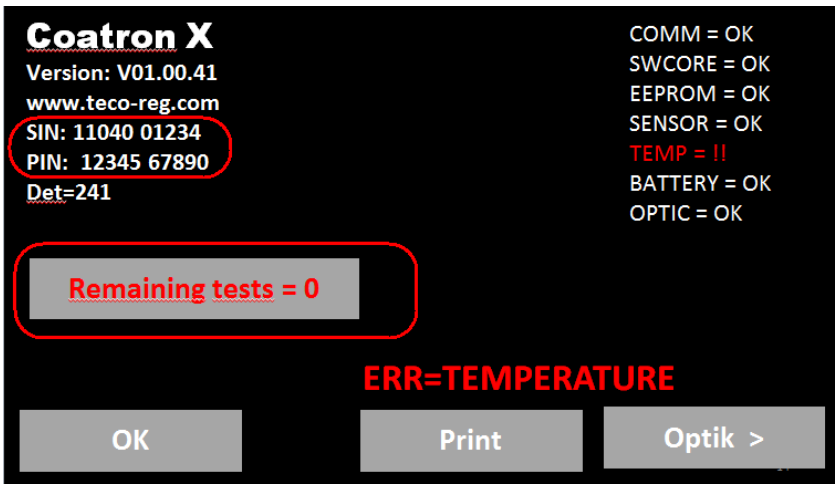



FIGURE 6: SYSTEM INFORMATION

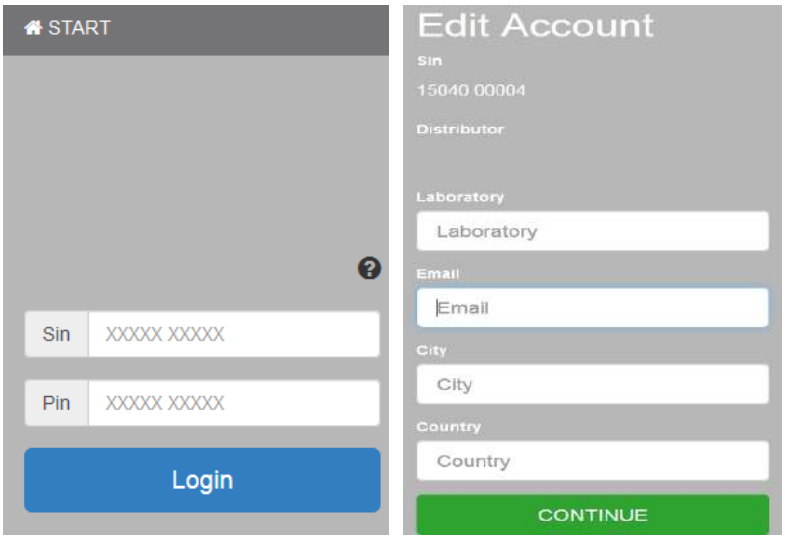



FIGURE 7: REGISTRATION OF COATRON-X

# 3. OPERATION OF THE **COATRON X**

## 3.1 HOMESCREEN

After boot or home button following screen is displayed

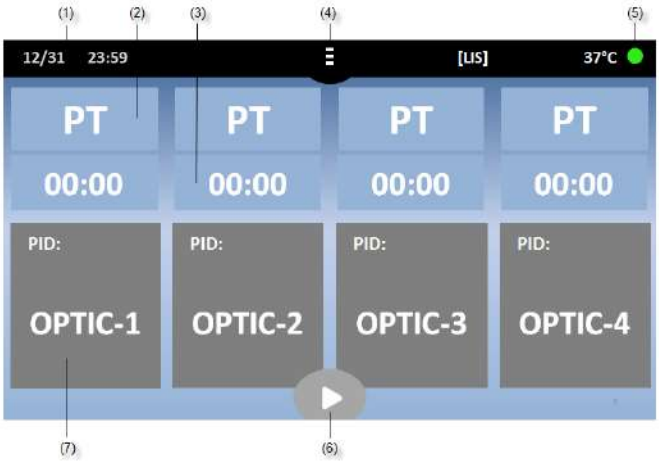



FIGURE 8: HOMESCREEN COATRON X TOP

| UI Element | Element Name | Use Function |
|---|---|---|
| (1) | Date & Time | Edit date |
| (2) | Current test | Change test |
| (3) | Stopwatch | Start/Reset stopwatch or countdown |
| (4) | Menu or Home | Open menu or return to main |
| (5) | Status Dot | Show device status/Open system information |
| (6) | Multistart | Activate all channels |
| (7) | Optic-Button | Channel-1 is idle. Touch to enter new PID and activate |
| | Active | Channel is active. Touch or add reagent to start |
| | Blinking green | Ongoing measurement. While green state it is allowed to touch, mix or move cuvette. |
| | Blinking orange | Ongoing measurement. Don't move nor touch cuvette. Touch button to stop measurement |
| | Current result | Touch to enter new PID |

| **Other functionality:** | |
|---|---|
| [LIS] | Visible, if connected with LIS |
| Green LED | System is ready for measurement |
| Red LED | Indicate system problems. No measurement is possible. |
| 37.0°C | Temperature on reagent block. |
| Grayed buttons | Use function is not possible during measurement. |
| Reduced brightness | Screensaver mode. Touch to reactivate. |
| Long touch | Repeat current function |
| Green<br>Yellow<br>Red | Green = Ready to measure, no problems<br>Yellow = Ready to measure, minor problems<br>Red = Not ready to measure, major problems |

## 3.2 INPUT PATIENT IDENTIFICATION

Call: Homescreen/Optic button

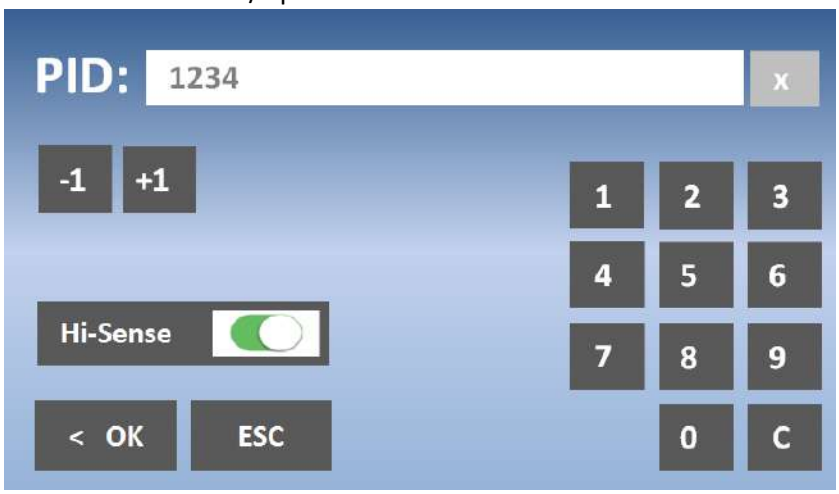



FIGURE 9: INPUT PATIETN ID

| Button | UI Element | Use Function |
|---|---|---|
| Numeric keys | 0-9, C, X | Change or delete PID. |
| Increment | -1 / +1 | Increment PID. Use long touch feature for easy change. |
| Hi-Sense | Hi-Sense | Enable very high detection sensitivity. Useful for high diluted or lipemic samples or "+++" results. |
| **Additional:** | | |
| Long touch | - | Press button > 2sec. |
| Sample barcode | - | Set PID to barcode. |

## 3.3 TEST SELECTION

Call: Homescreen/Test button

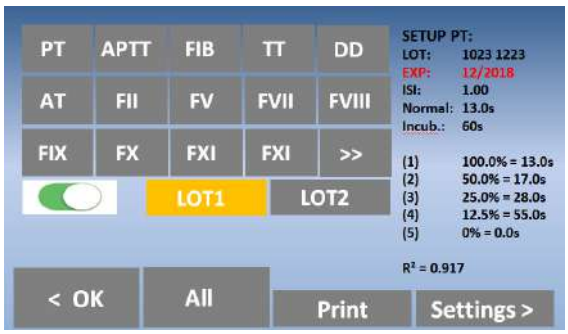



FIGURE 10: TEST SELECTION COATRON X PRO/TOP

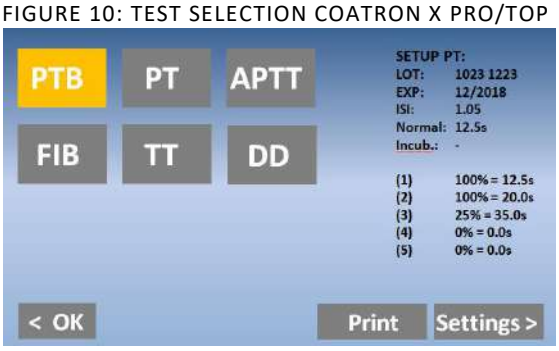



FIGURE 11: TEST SELECTION COATRON X ECO

| Button | UI Element | Use Function |
|---|---|---|
| Test keys | PT – F12<br>>> << | Select test.<br>Change test table |
| On / Off | On / Off | Activate two LOTs per test (not available for Coatron X Eco). |
| LOT 1/2<br>(not visible for DOACs) | LOT 1 / LOT 2 | Load calibration of LOT 1 or LOT 2 from memory. |
| OK | < OK | Confirm test for current channel. |
| All | All | Confirm test for all channels. |
| Settings | Settings > | Change test calibration. |
| Print | Print | Print current test testup. |
| Scan reagent barcode | - | Select current test and lot.<br>A long beep indicates an invalid barcode or LOT. |
| SETUP PT | Test Information Box | Calibration data of current lot and test.<br>Red values indicate invalid data. |

**About reagent barcode:**

The barcode on reagent label can be used to switch to correct Test and LOT. Before use of barcode, the test LOT + Calibration must be entered in calibration menu (see chapter test setting)

## 3.4 MEASUREMENT


FIGURE 12: SCREEN DURING MEASUREMENT

| Button (7) during measurment | |
|---|---|
| PID | Patient identification number (max 16 numbers). |
| Result | PT = 12.5s, 115% 0,91 INR. |
| Flag | f = very low fibrinogen (weak clot).<br>F = very high fibrinogen (strong clot).<br>* = Result is out of calibration.<br>X = double value deviate more than 15%. |
| Err | T = temperature not 36 - 38°C.<br>E = reagent expired.<br>S = light intensity very low; caused by turbid reagent and or high lipemic or icteric samples. |
| mOD | Current optical absorbance. A change of value > 50mOD indicates an ongoing clot reaction. |
| Timer | Current time of measurement. |
| Grey blinking | Optic is ready for start of measurement |
| Green blinking | Measurement is started,<br>but cuvette can be mixed or touched. |
| Orange blinking | Stop mixing and don't touch cuvette anymore |

## 3.5 SYSTEM SETTINGS

Call: Homescreen/Menu button


FIGURE 13: QUICKMENU COATRON X

| Button | Use Function |
|---|---|
| Auto PID | Enable/Disable the Auto PID feature. |
| Double determination (not visible for Coatron ECO) | Enable/Disable Double determination |
| Countown | Switch between Stopwatch and Countdown mode. |
| Results | Open the result history. |
| Setup | Open the system setup. |
| ⏻ | Put the device into sleep mode. |
| OK / 🏠 | Return to the home screen. |

**Auto PID:**

Using the Auto PID mode enables the user to let the device choose a consecutively numbered ID for every measurement. By setting the ID manually you set the start ID. Every new channel activation automatically sets the ID to the next higher number.

*Auto PID mode must be enabled to use the Multistart feature!*

**Double determination:**

When using double determination mode, the channels 1 / 2 (Coatron X Pro) respectively channels 1 / 2 and 3 / 4 (Coatron X Top) are combined to perform a test using the same ID twice. Both results are combined by calculating the mean value.

**Countdown:**

Use the stopwatches in countdown mode. The period of countdown is defined by incubation time of test (see “test settings”). When Countdown mode is enabled, the stopwatches count down give alarm 5sec before zero.

**Results:**

Pressing the Results button opens the result history screen.

**Setup:**

Pressing the Setup button opens the system settings.

 :

Pressing the Sleep Button sends the device into the sleep mode. To wake the device up, touch anywhere on the screen.

**OK Button /**  **:**

Pressing the OK or Home Button returns to the home screen.

Call: Homescreen / Menu / Setup


FIGURE 14: SYSTEM SETTNGS COATRON X PRO/TOP

| Setting/Buttons | Use Function |
|---|---|
| Date | Set system date, use long touch on "<" ">" to scroll through the values faster.<br>Short touch on date change the format (EU / US)<br>Long touch on date reset to defaut date |
| Time | Set the system clock. Long Touch the time to reset to default. |
| Language | Select the system language DE/EN/ESP/ITA/FR/RO/PL. |
| Mixer<br>(not visible for Coatron ECO) | Some reagents like PT sediment and need to be stirred Select here the mixer intensity (Low/Normal/High). Insert vial and magnetic stirbar into middle position. Change speed until stirbar ensures proper mixing. |
| Temp | Correct the actual current temperature of the reagent block. Long touch the temperature value will reset to default. Detailed information can be read in chapter "Adjust temperature". |
| OK / ⌂ | Return to the home screen. |
| Info | Open system information. |
| < / > | In or decrement value. Use long touch to scroll |

| | | | |
|---|---|---|---|
| EN, | English, | FI, | Suomi, |
| DE, | Deutsch, | HR, | Hrvatski, |
| ESP, | Espanol, | LV, | Latviesu, |
| ITA, | Italian, | LT, | Lietuviu, |
| FR, | Francais, | PT, | Portugues, |
| RO, | Romana, | SE, | Svenska, |
| PL, | Polski, | SK, | Slovensky, |
| DA, | Dansk, | SI, | Slovenscina, |
| NL, | Nederlands, | CS, | Cestina, |
| SR | Srpski | HU, | Magyar, |

## 3.6 TEST SETTINGS

Call: Homescreen / Test button / Settings

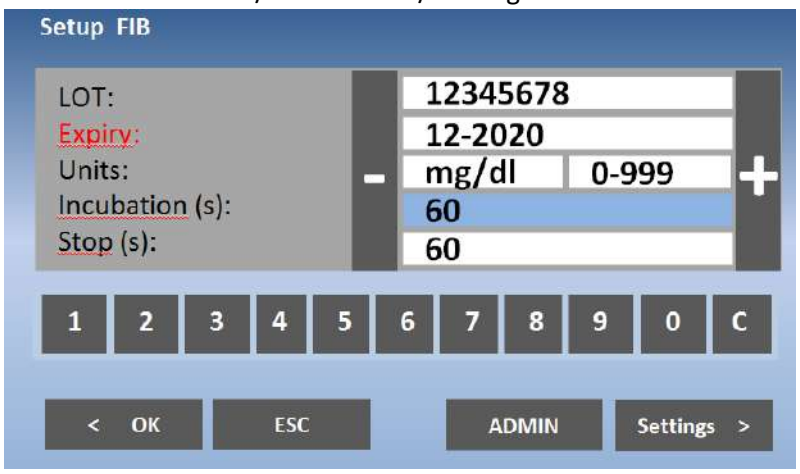



FIGURE 15: TEST SETTING 1

| Setting/Buttons | UI Element | Use Function |
|---|---|---|
| LOT | LOT Number field | Press the LOT text field to enter or change LOT number. |
| Expiry | Expiry date field | Press the expiry date value to select the field |
| Units | mg/dl<br>0-999<br>63 - 500 | Press to change unit<br>Result limited to unit range (min, max)<br>Result limited to calibrated range |
| Incubation | Incubation time field | Press the incubation value to select the field. |
| Stop | Stop time field | Press the stop time value to select the field. |
| In/Decrement | + or - | Change the value of the selected field. |
| Numeric keys | 0 – 9 and C | Keys for LOT entry. C=Clear |
| OK | < OK | Save settings and exit screen. |
| ESC | ESC | Exit to test selection without saving. |
| Admin | Admin | Open advanced test settings. Only visible for administrator user. |
| Settings | Settings > | Open test calibration settings (Screen test settings 2) |
| Barcode**:** | LOT barcode entry | Scan reagent barcode to input LOT and expiry. |

**LOT:**
Enter the LOT of the used reaganet for the selected test. If dual LOT is used, use the test selection screen to choose LOT 1 or LOT 2. Both LOT numbers have individual test settings.

**Expiry:**
Enter the expiry date of the reagent for the selected test (and LOT).

**Units:**
Value: Select the units used for the test results. The available unit is predefined for each test.
Range: Limit results to unit or calibration range. Results out of range are reported as “>Max” or “<Min”.

**Incubation:**
Required waiting time until adding final reagent and start measurement. The time is used for countdown.

**Stop:**
Some samples do not clot. Afer stop time instrument breask measurement and report "+++" (no clot detect)

Call: Homescreen / Test button / Settings / Settings

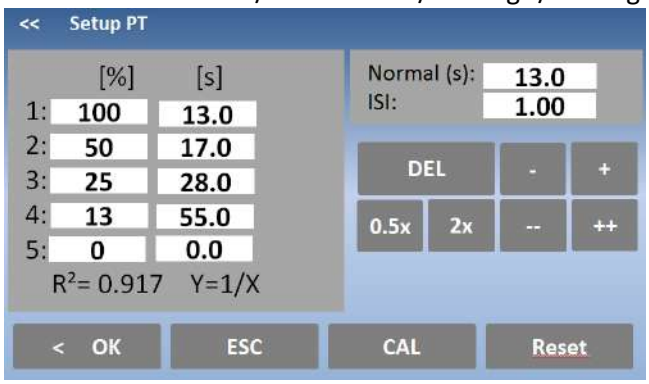



FIGURE 16: TEST SETTING 2

| Setting/Buttons | UI Element | Use Function |
|---|---|---|
| Calibration curve values | Value fields | Press a calibration value to select the field. |
| Increment Decrement | +, -, ++, -- | Change values in small or big steps.<br>Use long touch to repeat change |
| Double/Half | 0.5x 2x | Half or duplicate values |
| Delete | DEL | Delete the selected value. |
| Reset | Reset | Reset all values to default. |
| Calibrators | CAL | Shift all calibration points according to serial dilution (1:1 1:2 1:4 …) |
| OK | < OK | Save settings and exit screen. |
| ESC | ESC | Exit screen without saving. |

**Calibration curve:**
Input of Calibration points. Minimum 2 points, maximum 5 points.

**Normal:**
Reference value for normal clotting time like for PT (MNPT). Only shown, if unit is selected.

**ISI:**
International sensititivity index of PT reagent. Value is stated on reagent label.

**$R^2$:**
Linearity of calibration depending on mathematic

| | | | |
|---|---|---|---|
| $R^2$<0.5 | not linear | Y=LIN | linear interpolation |
| $R^2$<0.9 | moderate linear | Y=1/X | reciprocal linear interpolation |
| $R^2$>0.9 | high linear | Y=logXY | double logarithm interpolation |

## 3.7 REVIEW RESULTS

The device holds automatically the recent 180 results into EEPROM memory. The most recent result is shown first. If the result history exceeds the memory, then the oldest measurement result is overwritten.

Call: Homescreen / Menu / Results

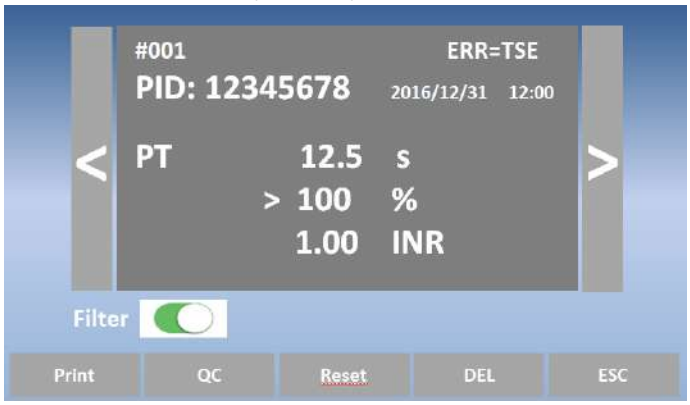
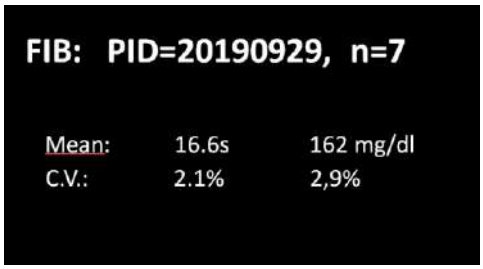



FIGURE 17: REVIEW RESULTS

| Setting/Buttons | Use Function |
|---|---|
| < > | Scroll the results. |
| Filter (on,off) | Scroll only current PID+Test |
| Print | Print the shown result. |
| QC<br>  <br>FIB: PID=20190929, n=7<br>Mean: 16.6s 162 mg/dl<br>C.V.: 2.1% 2,9%<br>FIGURE 18: QC REPORT | Print & display max. 14 values of current PID+Test including mean and C.V. value.<br>QC REPORT<br>26.09.2019<br>System: Coatron X<br>SIN : 01040 01234<br>Test: FIB<br>PID: 20190929<br>---<br>1 16.8s 159 mg/dl<br>2 17.1s 154 mg/dl<br>3 16.9s 157 mg/dl<br>4 16.2s 166 mg/dl<br>5 16.5s 163 mg/dl<br>6 16.4s 164 mg/dl<br>7 16.1s 168 mg/dl<br>---<br>-<br>Mean: 16.6s 162 mg/dl<br>C.V. : 2.1% 2.9% |
| Reset | Reset the result view to most recent result. |
| DEL | Delete current result |
| ESC | Exit screen. |

# 4. BASIS COAGULATION TESTS

*This section describes only rudimental how to run basic clotting tests on Coatron. Correct procedure may be different for specific reagents. Read and follow always the procedure in boxinsert of reagent kit.*

## 4.1 QUICKGUIDE OF PT DETERMINATION

How to run a PT measurement:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Reconstitute PT reagent and wait 30-60 min before next step.
3. Place PT vial into reagent block + stirring bar and let incubate for at least 5min.
4. Change test of channel 1 to “PT” by pressing on the current test.
5. Place empty cuvette into optic.
6. Pipet 25µL of sample into cuvette.
7. Press “00:00” to start the stopwatch and wait 30 seconds.
8. Press specific “OPTIC” and enter a PID or scan a sample barcode.
9. Add 50µL PT reagent, when “Active” is blinking. The measurement will start automatically when adding the reagent.
10. Wait for result or touch optic button to abort.

Multi-Activation (not for Coatron ECO)

1. Open menu and set Auto PID = On.
2. Place empty cuvettes into each channel and pipet 25µL of sample to each cuvette.
3. Press button multistart.
4. Add 50µl PT in to each cuvette from left to right.

How to calibrate a PT

1. Reconstitute calibrator and wait 15-30min before continue with next step
2. Calibrators
   The target value of calibrator is state at certificate. I assume 100% as example
   IBS, Owrens or $NaCl_2$ solution can be used as sample diluent
   a. 100%: Pipet 100µl calibrator into empty tube
   b. 50%: Pipet 100µL 100% calibrator + 100µL diluent into empty tube
   c. 25%: Pipet 100µL 50% calibrator + 100µL diluent into empty tube
   d. 12.5%: Pipet 100µL 25% calibrator + 100µL diluent into empty tube
3. Run all 4 calibrators like patients and write down the clotting time
   (double determination is recommended)
4. Enter PT settings and enter
   a. correct LOT, Exp (read Barcode of vial label)
   b. set UNITS to “INR + %”
   c. Input Normal Time (=100% result) + ISI (see vial)
   d. Input % calibration

## 4.2 QUICKGUIDE OF PT-B DETERMINATION

How to run a PT-B measurement from finger blood:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Change test to “PTB” by pressing on the current test.
3. Reconstitute PT-B with component-1 (Diluent) and wait 30-60 min before next step.
4. Add component-2 ($CaCl_2$) to PT-B and wait again for 30-60 min before next step.
5. Place empty cuvette into optic or pre-incubation.
6. Pipet 150µL of PT-B into cuvette. The cuvette must be used within the next 10min.
7. Close PT-B vial and store in the refrigerator until next use. The reagent is stable for 30 days.
8. Press “OPTIC-1” and enter a PID or scan a sample barcode.
9. When “active” is blinking, pierce the finger and pipet 15µL capillary blood from finger into cuvette.
10. Measurement should start. It is important to mix in the cuvette. For this lower the pipet into cuvette and pump 10-15x up and down. Stop mixing latest when countdown is zero.

How to calibrate a PTB

1. Reconstitute calibrator with 1.7mL and wait 15-30min
2. Calibrators
   The target value of calibrator is state at certificate. I assume 100% as example
   IBS, Owrens or NaCL solution can be used as sample diluent
   a. 100%: Pipet 100µl calibrator into empty tube
   b. 25%: Pipet 100µL 100% calibrator + 500µL diluent into empty tube
3. Run all calibrators like patients and write or print the clotting time
4. Enter PTB settings and enter
   a. correct LOT, Exp
   b. set UNITS to “INR + %”
   c. Input Normal Time (=100% result) + ISI (see vial)
   d. Input % calibration

## 4.3 QUICKGUIDE OF APTT DETERMINATION

How to run an aPTT measurement:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Change test to “APTT” by pressing on the current test.
3. Place CaCl into instrument let incubate for at least 5min.
4. Place empty cuvette into optic or pre-incubation.
5. Pipet 25µL of sample into cuvette.
6. Pipet 25µL of cold aPTT reagent into cuvette.
7. Press “00:00” to start the stopwatch and wait 180 seconds.
8. Short before end of incubation press “OPTIC-1” and enter a PID or scan a sample barcode.
11. Add 25µL CaCl, when “Active” is blinking. The measurement will start automatically.
12. Wait for result or touch optic button to abort.

## 4.4 QUICKGUIDE OF FIB DETERMINATION

How to run a FIB measurement:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Change test to “FIB” by pressing on the current test.
3. Reconstitute FIB reagent and wait 30-60 min before next step.
4. Place FIB vial not into reagent block. Room temperature is ok.
5. Place empty cuvette into optic.
6. Pipet 10µL of sample into cuvette.
7. Pipet 90µL of IBS buffer into cuvette.
8. Press “00:00” to start the stopwatch and wait 30 seconds.
9. Press “OPTIC-1” and enter a PID or scan a sample barcode.
10. Add 50µL FIB reagent, when “Active” is blinking. The measurement will start automatically when adding the reagent.
11. Wait for result or touch optic button to abort.

How to calibrate a FIB

1. Reconstitute calibrator and wait 15-30min before continue with next step
2. Calibrators
   The target value of calibrator is state at certificate. I assume 300mg/dL as example

   a. 600mg/dL: Pipet 50µl calibrator + 200µL IBS buffer into empty tube
   b. 300mg/dL: Pipet 50µl calibrator + 4500µL IBS buffer into empty tube
   c. 150mg/dL: Pipet 50µl calibrator + 950µL IBS buffer into empty tube
   d. 75mg/dL: Pipet 50µl calibrator + 1950µL IBS buffer into empty tube

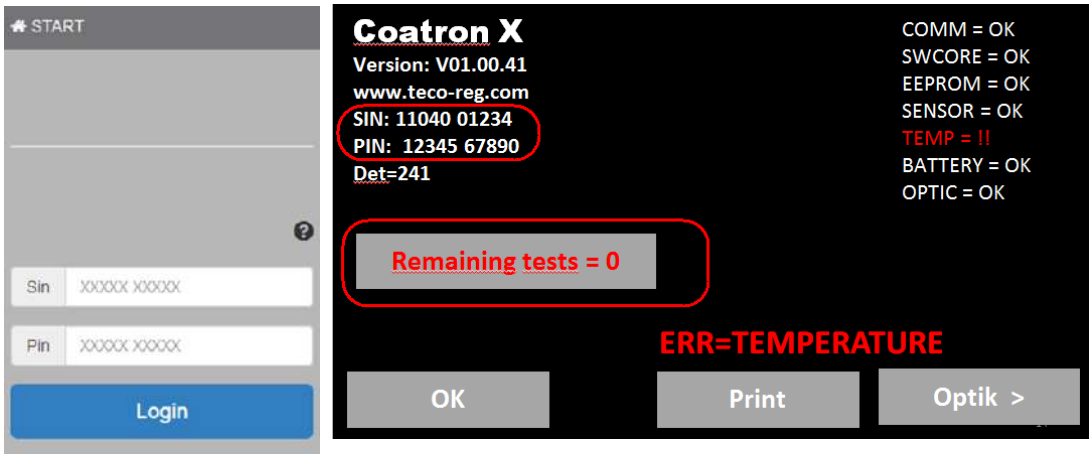
3. Run all 4 calibrators
   a. Add 50µL of calibrator into cuvette
   b. Add 25µL of FIB reagent to start measurement. Write clotting times to paper or print,

4. Enter FIB settings and enter
   a. correct LOT, Exp
   b. set UNITS to “mg/dL”
   c. Input mg/dl calibration

# 5. TICKET SYSTEM

## 1) Login to ticket system

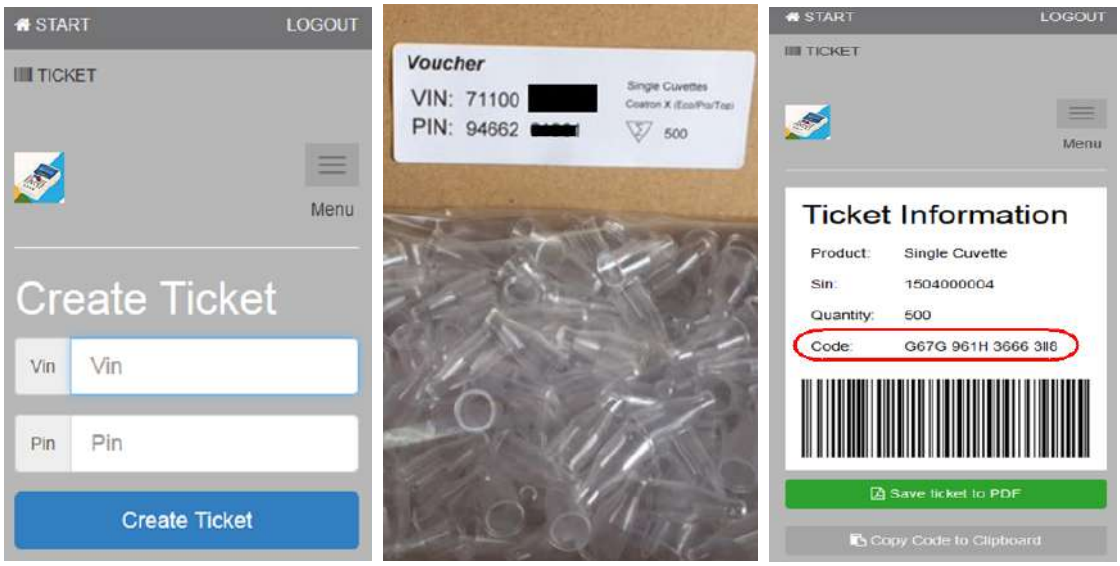
webpage: www.teco-reg.com




**Enter SIN and PIN of instrument! This information can be found on instrument license plate (Type label) or on info screen.**

FIGURE 19: TICKET SYSTEM, LOGIN

## 2) Input Voucher



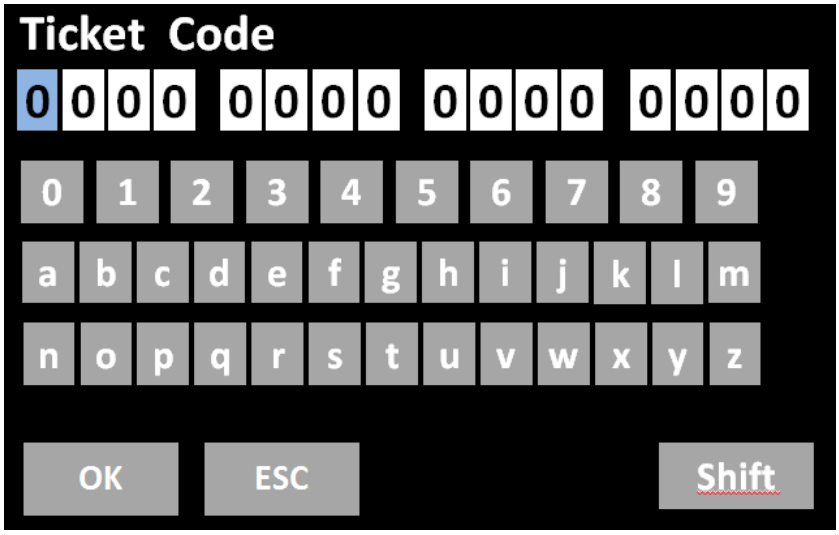

**Enter VIN and PIN of voucher**

**Voucher is inside of cuvette box**

**Transfer Ticket code to instrument**

FIGURE 20: TICKET SYSTEM, VOUCHER

## 3) Transfer ticket code to instrument




**Open info screen (touch blinking RED LED) and then "Remaining tests=0". The code can be transfered by manual input, barcode scanner or TECAM SMART software.**

FIGURE 21: TICKET SYSTEM, INPUT CODE

## 4) Using TECAM SMART software

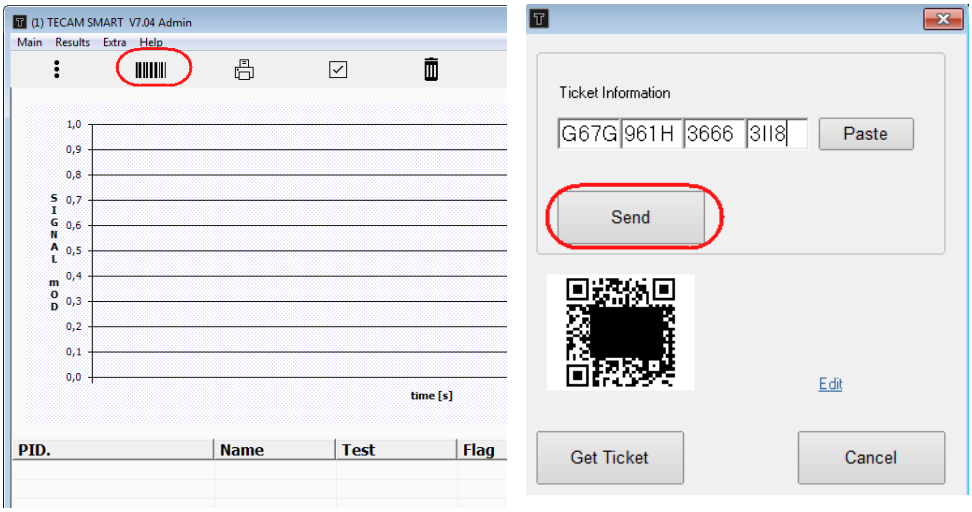



FIGURE 22: TICKET SYSTEM, TECAM SMART

a) Use your mobile device and scan QR code or "Get ticket", if TECAM is connected to internet

b) Follow dialogue according to chapter (1)

c) Copy Paste the code and "send" to instrument

# 6. SERVICE FUNCTIONS

*Only for authorized and trained persons. Unqualified modifications can cause troubles and misfunction of the system!*

## 6.1 SYSTEM INFORMATION

Call: Homescreen / green or red LED

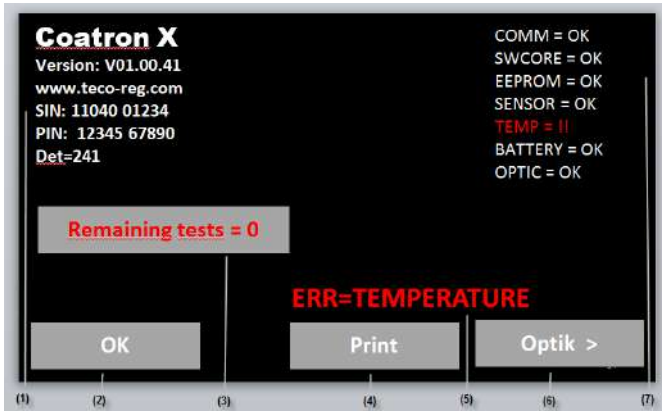



FIGURE 23: SYSTEM INFORMATION

| UI Element | Element Name | Use Function |
|---|---|---|
| (1) | - | System version information |
| (2) | OK | Return to homescreen |
| (3) | Remaining tests | Number of activates cuvettes.<br>Touch to activate new cuvettes |
| (4) | Print | Print out of system information |
| (5) | ERR message | Show current error |
| (6) | Optik | Check optic system |
| (7) | - | System error information |

**System information**

Version of software, URL link to register or ticket system, system ident number (SIN), product ident number (PIN). SIN+PIN is required for login to ticket system.

**Remaining tests=0:**

Latest at zero the system will stop operation and require to activate new cuvettes.

**YELLOW warnings**

Minor problems

| | |
|---|---|
| Reagent expired | Check expiry date of test |
| Remaining tests < 100 | Activate cuvettes soon |

**RED warnings**

System is not ready to measure

| | |
|---|---|
| COMM= communication to LIS | SWCORE = software memory overflow |
| EEPROM= EEPROM/memory error | SENSOR = temperature sensor |
| TEMP= temperature not 36-38°C | BATTERY = CR2032 on mainboard below 3V |
| OPTIC= optical system out of range | |

## 6.2 OPTIC CHECK

Call: Homescreen / green or red LED / Optic

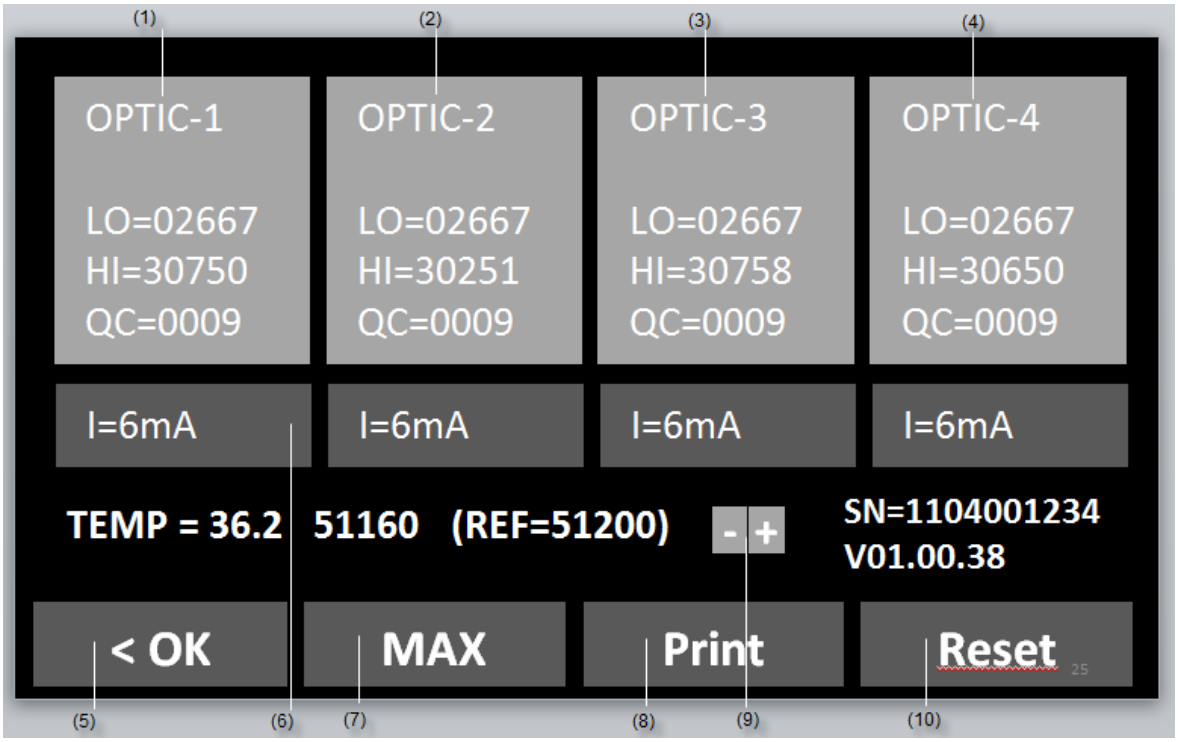



FIGURE 24: OPTIC CHECK

| Button | Caption | Use Function |
|---|---|---|
| (1)-(4) | OPTIC xx | Reset QC value |
| (5) | I=mA | Display and change intensity of LED |
| (6) | OK | Return to homescreen |
| (7) | MAX | Set all LED to max. intensity (42mA) |
| (8) | Print | Print system report (see next chapter) |
| (9) | + / - | Change temperature |
| (10) | Reset | Reset all channels and re-calibrate optic |

| Informations on screen | | Fault condition | Troubleshoot |
|---|---|---|---|
| LO | optic signal, when LED is off | > 2900 | Replace optic board |
| HI | optic signal, when LED is on | < 25000 | Remove cuvette and touch "RESET" |
| QC | noise of optic signal | > 30 | Touch button "OPTIC" |
| mA | power of LED (intensity) | not [3 - 12mA} | Remove cuvette and touch "RESET" |
| TMP | temperature in °C | not [36.0 - 38.0°C] | wait 15min |
| REF | signal of temperature sensor | not [48000 - 52000] | adjust temperatur or replace sensor |

## 6.3 SYSTEM REPORT

Call: Homescreen / green or red LED / Print

```
SYSTEM REPORT

08.10.2019

System:         Coatron X
Version:        V01.03.49 (OEM-1D)
SIN :           01040 01234
PIN:            12345 67890

TEMP:           37.0°C
                50981  (target=51000)

Optic:
  Lo     Hi      mA     Qc
-----------------------------------------------
1:2698  28822   5      1      OK
2:2698  29822   6      1      OK
3:2698  30822   7      1      OK
4:2698  29822   6      1      OK

PT=     123
aPTT=   102
FIB=    100
DD=     0
AT=     0

TOTAL   325
```

Date of report

name of system
software version and OEM Index
system ident number
product ident number

temperature of optic and digital value
of thermosensor

Optical values
Lo= LED off
Hi= LED on
mA= LED power
Qc= noise of optic
OK= no fault
!!= fault condition

count of performed tests

Fault condition are described in chapter “optic check”

## 6.4 ADJUST TEMPERATURE

Call: Homescreen / Menu / Temperature

1. Switch on device and wait approx. 15min until system show 37°C on screen.

2. Fill a reagent tube/vial with 2 ml water and place it in a reagent position. Place a digital thermometer in the reagent tube and let warm-up for approx. 10 min.

3. Press menu
   Change current system temperature to value of thermometer. Wait 10min and repeat procedure.

   Typical problems:

| Malfunction / Error | Possible cause | Measures |
|---|---|---|
| System heat not up to 37°C | Sensor calibration is out of range | Reset to factory default as described in chapter “Hidden Function” |
| System show 0.00°C | Sensor is out of range | Ambient temperature must be 0 – 45°C. |
| | Sensor or optic LED board is defect | Replace LED board. |

## 6.5 FIRMWARE UPDATE

*Only for authorized and trained persons. Sudden interruption of power or data communication during update procedure will cause device not to boot anymore. In this case, the instrument can be restored only by JTAG interface.*

1. Download flashdisk.exe from manufacturer website. Contact local distributor to receive correct URL address.

2. Flashdisk.exe is a selfrunning Winzip archive. A double click will start the update dialogue. Some antivirus software may block selfrunning archiv. In this case extract the file to your desktop and execute “XFlash.exe”

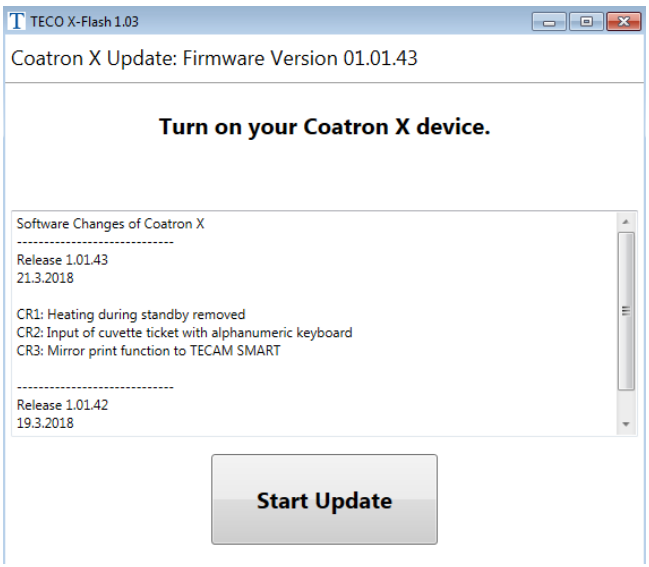



FIGURE 25: SCREENSHOT OF XFLASH TOOL

3. Confirm “Start Update”

4. Remove USB cable from instrument and confirm

5. Connect USB cable to instrument USB “Service” (=second USB port from left)

   XFlash will now identify the instrument and display “CONTINUE”. Abort XFlash, if no instrument is found and install device driver “FT232.exe” manually. The file is included in the flashdisk archive.

6. Confirm “Start Update”. After this command the firmware will be transmitted to instrument. There is no way to interrupt. After around 120s the update will be finished.

7. Remove power and afterward USB cable from service port. Now connect power to instrument. It should boot and show correct firmware version.

## 6.6 OVERVIEW OF MAINBOARD

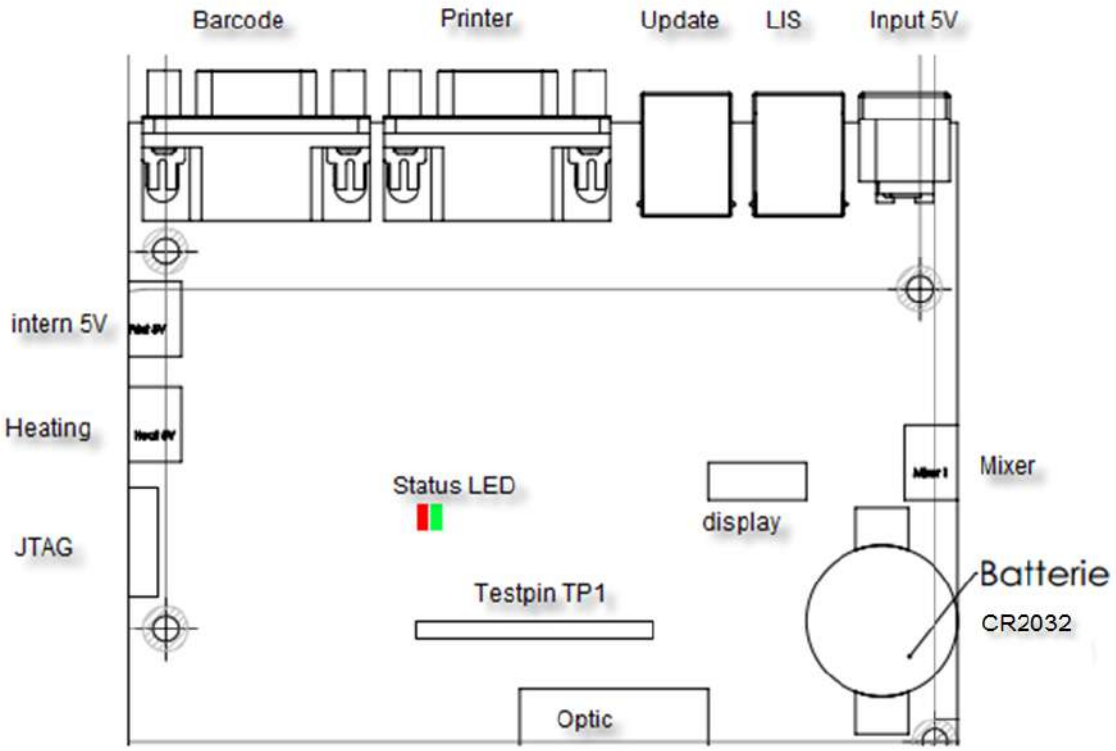



FIGURE 26: MAINBOARD

Testpin Function:

TP1 = Systick Interval, must toogle each 1ms
TP2 = indicate reading of SD24
TP3 = draw homescreen
TP4 = Write to EEprom
TP5 = Read from to EEprom
Other = not used

Status LED:

| | | |
|---|---|---|
| green, permanent | = everything OK | |
| red, permanent | = EEPROM error | defect optic unit and/or mainboard |
| green, blink | = Battery < 3.0V | battery expired |
| red, blink | = Temp sensor | Optic not connected |

## 6.7 TYPICAL FAILURES

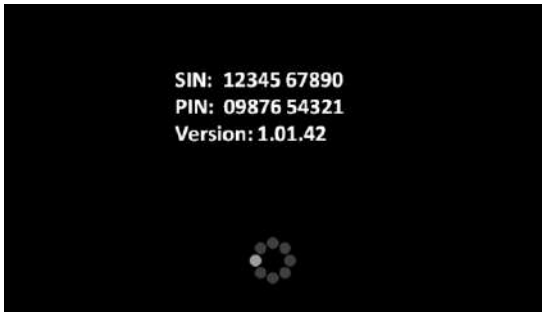
| Malfunction / Error | Possible cause | Measures | By |
|---|---|---|---|
| System not ready | different | Open system info and check red errors | User |
| Remaining tests = 0 | No cuvette activated | Create a ticket | User |
| ERR=Comm | Mainboard defect | replacement | Authorized service |
| ERR=SWCORE | Software failure or bug | Update firmware | User |
| ERR=Sensor | Temp sensor defect | Replacement of optic | Authorized service |
| ERR=Temp | Temperature out of 36-38°C | Wait 15min | User |
| ERR=Optic | Optic channel blocked or LED defect | Remove cuvette from optic or clean optic or replace optic | Authorized service |
| ERR=Battery | Battery low power | Replacement | Authorized service |

| False results | Possible cause | Measures |
|---|---|---|
| No or false clot detected | True, patient anti coagulated or bleeding | Remove cuvette and check with needle for clot |
| | Reagent defect | Check reagent with eyes for flakes or clots. Run control plasma to verify. Prepare new vial. Check diluent/water |
| | Instrument missed clot | Increase MAX time |
| | Low fibrinogen or optical interference (lipemic, bilirubin, haemolytic) | Repeat but activate hi-sense option |
| False result (INR, %, mg/dl, ...) | Method not correct calibrated | Check calibration data and correct LOT |

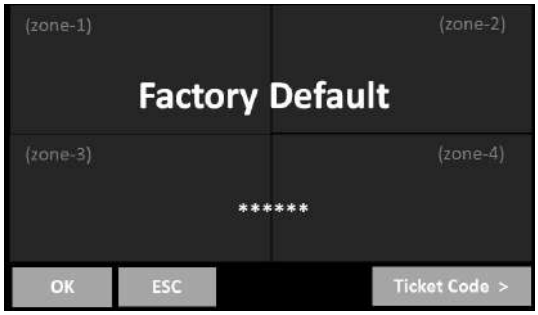
| Invalid cuvette ticket | Possible cause | Measures |
|---|---|---|
| LOT invalid | The voucher ticket already has been used on system. | Use a new voucher www.teco-reg.com |
| S/N invalid | The SIN number of voucher ticket information is not equal to S/N of instrument | Enter the voucher ticket code only on the correct target device |
| Code16 invalid | System does not accept Code16 | Re-use voucher @ (www.teco-reg.com) to obtain Code20 voucher tickets. |
| Invalid | System does not accept voucher ticket for an unknown reason | Visit www.teco-medical.com\support and "report a problem". Provide information about VIN , SIN and Code20. |

# 7. RESET TO FACTORY DEFAULT

**System factory reset procedure:**




WELCOME SCREEN +




FACTORY DEFAULT

How to reset to factory default:

1. Press 3sec to spinner during boot up
2. Select “OK” Switch on device and switch to home screen
3. Confirm the reset

⇨ Date, temperature and test calibration must be adjusted after a factory reset!!

Default values:

- Temperature sensor = 51000
- Mixer = 1;
- Language = EN;
- Double determination = OFF;
- Auto PID = ON;
- Countdown = OFF;
- All results stored on board are deleted
- All test calibration data are reset to default

Test calibration:

How to reset to factory input a PT calibration:

1. Switch on device and switch to home screen
2. Touch any test button
3. Change test to “PT” and touch “Setup” or scan barcode of PT vial
4. Enter LOT, expiry and select Units to “% + INR”

# 8. WORKING WITH TECAM SMART

> ⇨ Detailed information about installation and operation be be read in the online manual of TECAM. This is just a quick overview.

TECAM software is a small local LIS and combines laboratory data management, quality control and research purpose in one. It connects the Coatron to the “big” LIS and and manange results in an own local database. Flexible filters allow QC with Levey-Jennings graph and Westgard analysis. Each result can be traced back to reagent lot and calibration.

| Features | Smart |
|---|---|
| Receive result from analyser | The results can be reported and manage in a locl database |
| Receive calibration curve from anaylser | Visualize and manage calibration data for all reagents and LOT. |
| Receive reaction curve | Visualize the optical reaction for research, result verification or failure anaylsis |
| Patient information | Connect Patient-ID with name and other information. |
| LIS communication | Talk to LIS with ASTM-1394 standard protocol<br><br>Receive from LIS: Patient information<br>Send to LIS: Results |
| Statistical analyze (QC) | Power filters allow quality evey-Jennings graph and Westgard analysis for controls as well as for patients |
| integrated TECMONI | This is a powerful research tool to visualize raaction curve in real time. It is a great tool for reagent development or adapting nee tests to instrument |
| Mirror print | Instead of expensive portable thermo printer, use TECAM as printer |
| Ticket system | Activation of cuvette in its easiest way. Connect to ticket system, receive ticket and send to instrument |

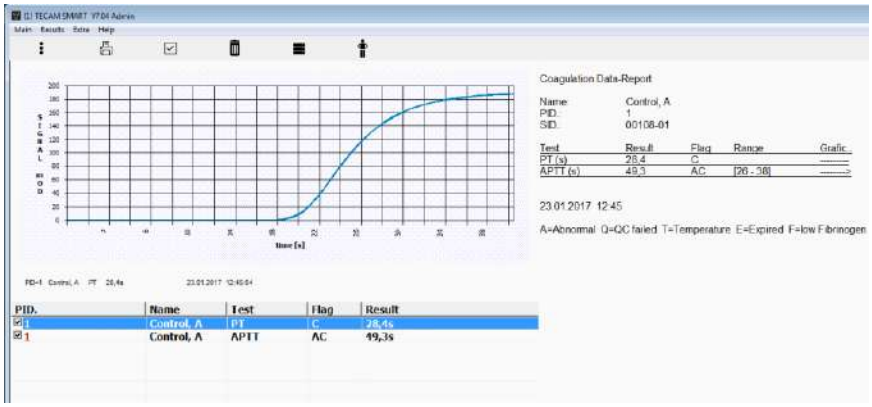



FIGURE 27: TECAM SMART

# 9. CLEANING AND MAINTENANCE

## 9.1 GENERAL CLEANING INFORMATION

- Clean with a lint free cotton cloth or stick
- Never pure any liquid into optic, working area or touch display
- Keep the device free of dust and moisture.
- If the device is soiled with liquids, remove the soiling with an absorbent cloth.
- If a liquid has accidentally been spilt or pipetted into a measurement channel, remove power immediately and clean the measurement channel with pipette and a lint-free cloth. Check the function of the optics in the menu SERVICE

Regard all surfaces and materials, which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.

Avoid any direct contact with decontaminants or disinfections.

## 9.1 CLEANING

- Use microfiber tissue only and no liquid to clean the screen
- Clean and wipe up all spills around the working area with 5-10% diluted bleach detergent or water.

## 9.2 DECONTAMINATION

- Use 30% diluted bleach and commercial disinfectant (e.g. Bacillol®AF)
- Decontaminate working area. Don’t apply liquid on display.

## 9.3 REGULAR MAINENTANCE

- No maintenance required

# 10. TECHNICAL DATA

| | | |
|---|---|---|
| **Analyzer** | | |
| Display | | capacitive touch sensitive TFT 4.3'' 480x272 |
| Measurement system | | 1-4 independent measurement channels<br>wavelength of LED 405 nm / 620 nm |
| Cuvette | | single channel cuvette for optical detection |
| Positions (prewarmed) | | 5 reagent positions at 36.5 – 37.5 °C<br>20 cuvette positions at 36.5 – 37.5°C |
| Reaction volumes | | Minimum total volume is 75 µl |
| **Power supply** | | |
| Input Power | | 100 – 240VAC/50-60Hz/600-300mA |
| Output Power | | 5V DC, 5A |
| Batterie (mainboard) | | Lithium CR2032 3V |
| Power consumption | | max. = 14W sleep < 0.5W |
| **Dimensions** | | |
| Size (W x D x H) | | 225 x 150 x 90 mm |
| Weight | | 1.04 kg (without power supply) |
| **Ambient conditions** | | |
| See chapter "Installation" | | |
| **Noise output** | | |
| Operating noise | | max. 50 dBA |
| **Interfaces** | | |
| RS232 (Barcode) | | Sub-D9, female; 9600 Baud/8/1/N; Pin-9 powered with 5V DC. For external handheld barcode scanner, serial printers |
| RS232 (Printer) | | Sub-D9 female; 9600 Baud/8/1/N; For serial printers |
| USB (Service, Firmware Update) | | Type-B, female, 115200 Baud/8/1/N |
| USB (LIS) | | Type-B, female, 115200 Baud/8/1/N; For LIS communication |
| **Typical performance data** | | |
| Test | CV. | Range |
| PT | <3% | 0-30 INR |
| APTT | <3% | 15 – 420s |
| FIB | <7% | 50-999mg/dL |

# 11. INDEX

CE

# KONFORMITÄTSERKLÄRUNG

# DECLARATION OF CONFORMITY

Doc#007/11-2021

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 Produkte – IVD-Blutgerinnungsmessgeräte,
*declare under our own responsibility, that the products – IVD Coagulation analyzers*

## Coatron A4

Bezeichnung, Typ oder Modellname / *name, type or model*

Alle anwendbaren Anforderungen der folgenden Richtlinien entsprechen:

1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 –"alle anderen Produkte"
2. Richtlinie 2014/30/EU über Elektromagnetische Verträglichkeit
3. Richtlinie 2011/65/EU RoHS III

*Standards and regulations applied:*

1. *Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products"*
2. *Directive 2014/30/EU on electromagnetic Compatibility*
3. *Directive 2011/65/EU RoHS III*

Weitere angewandte Normen:

| | |
|---|---|
| 4. Sicherheit: | EN 61010-2-101:2002 |
| 5. Risikomanagement: | DIN EN ISO 14971:2019 |
| 6. Informationen: | EN ISO 18113-3:2011 |
| 7. Medizingeräte-Software - Lebenszyklus-Prozesse: | DIN EN 62304:2016 |

*Further related standards:*

| | |
|---|---|
| *4. Safety:* | *EN 61010-2-101:2002* |
| *5. Risikmanagement:* | *DIN EN ISO 14971:2019* |
| *6. Information:* | *EN ISO 18113-3:2011* |
| *7. Medical device software - life-cycle processes:* | *DIN EN 62304:2016* |

Das QM-System des Herstellers ist zertifiziert nach:

**EN ISO 13485:2016**

*The QM-system of the manufacturer is certified for:*

***EN ISO 13485:2016***

Konformitätsbewertungsverfahren:

Gemäß Anhang III der Richtlinie 98/79/EG

*Conformity assessment procedure:*

*According to Annex III of Directive 98/79/EC*

Ort und Datum der Unterzeichnung: Neufahrn, 11.11.2021
Place and date of issue: Neufahrn, November 11, 2021

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

# 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 / *Double cuvette* | Ref. 19 000 02 |
| Einzelküvette / *Single cuvette* | Ref. 20 000 02, 24 100 00 |
| 4-fach Küvette / *Cuvette 4 pos/ea* | Ref. 80 521 10 |
| 6-fach Küvette / *Cuvette 6 pos/ea* | Ref. 80 560 00 |
| 6-fach Küvette (micro) / *Cuvette 6 pos/ea (micro)* | 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 artivel 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

Medical Instruments TECO Production+Trading GmbH

Matthias Dieckmann
General Manager

TECO
MEDICAL INSTRUMENTS
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Neufahrn, 26/04/2018

**TO WHOM IT MAY CONCERN**

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

Medical Instruments
TECO
Production+Trading GmbH

Christian Hoetzl
General Manager
TECO Germany

TECO

CE

# KONFORMITÄTSERKLÄRUNG
# DECLARATION OF CONFORMITY

Doc#200/12-2023

| | |
|---|---|
| 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 – 24 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 /- 24 IVD) 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, 2023-12-20
Place and date of issue:

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC



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Doc#200/12-2023

# 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<br>EUDAMED DI |
|---|---|---|---|---|---|
| 1 | A0230-010 | TEClot PT-S (Quick) | 5x2ml | Prothrombin time ( quick test ) | W0103020101 / 30539<br>B-PTS-A0230-010WW |
| 2 | A0230-040 | TEClot PT-S (Quick) | 10x4ml | Prothrombin time ( quick test ) | W0103020101 / 30539<br>B-PTS-A0230-040X7 |
| 3 | A0230-100 | TEClot PT-S (Quick) | 10x10ml | Prothrombin time ( quick test ) | W0103020101 / 30539<br>B-PTS-A0230-100WY |
| 4 | A0260-050 | TEClot PT-B (Owren) | 5x10ml | Prothrombin time RT & POC | W0103020801 / 55986<br>B-PTB-A0260-050G2 |
| 5 | A0320-050 | TEClot APTT-S | 10x5ml | Activated partial thromboplastin time | W0103020102 / 55982<br>B-APTTS-A0320-050AM |
| 6 | A0401-020 | TEClot TT | 10x2ml | Thrombin time / reptilase / batroxbin time | W0103020103 / 55988<br>B-TT-A0401-0207P |
| 7 | A0511-020 | TEClot FIB | 10x2ml | Fibrinogen assays (factor i) | W0103020201 / 55997<br>B-FIB-A0511-020N2 |
| 8 | A0511-050 | TEClot FIB | 10x5ml | Fibrinogen assays (factor i) | W0103020201 / 55997<br>B-FIB-A0511-050NB |
| 9 | C1010-020 | TEChrom AT | 6x6ml reagent FXa<br>3x3 ml substrate | Antithrombin | W0103020602 / 56156<br>B-AT-C1010-020HL |
| 10 | D2010-012 | Red D-Dimer | 3x4ml latex<br>3x7ml reaction buffer | D-Dimer | W0103020503 / 47349<br>B-DD-D2010-0126W |
| 11 | D2020-005 | Blue D-Dimer LC | 1x5ml latex LC<br>1x7ml reaction buffer | D-Dimer | W0103020503 / 47349<br>B-DD-D2020-0057E |
| 12 | P8001-005 | TECal N | 5x1ml | Calibration plasma for haemostasis | W0103020701 / 45786<br>B-CAL-P8001-005X8 |
| 13 | P8200-005 | TECal DD | 5x1ml | Calibration plasma for haemostasis | W0103020701 / 47348<br>B-CAL-P8200-005XX |
| 14 | P6001-010 | TEControl N | 10x1ml | Control plasma for haemostasis | W0103020702 / 30590<br>B-CTRL-P6001-010H7 |
| 15 | P6101-010 | TEControl A | 10x1ml | Control plasma for haemostasis | W0103020702 / 30590<br>B-CTRL-P6101-010HQ |
| 16 | P6201-010 | TEControl A Plus | 10x1ml | Control plasma for haemostasis | W0103020702 / 30590<br>B-CTRL-P6201-010J9 |
| 17 | P5001-010 | TEClot Factor II | 10x1ml | Coagulation factor ii ( prothrombin ) | W0103020202 / 30542<br>B-FAC-II-P5001-010ML |
| 18 | P5101-010 | TEClot Factor V | 10x1ml | Coagulation factor v | W0103020204 / 30544<br>B-FAC-V-P5101-010AN |
| 19 | P5201-010 | TEClot Factor VII | 10x1ml | Coagulation factor vii | W0103020205 / 30545<br>B-FAC-VII-P5201-0107B |
| 20 | P5301-010 | TEClot Factor VIII | 10x1ml | Coagulation factor viii | W0103020207 / 30547<br>B-FAC-VIII-P5301-01097 |
| 21 | P5401-010 | TEClot Factor IX | 10x1ml | Coagulation factor ix | W0103020208 / 30548<br>B-FAC-IX-P5401-0106C |
| 22 | P5501-010 | TEClot Factor X | 10x1ml | Coagulation factor x | W0103020209 / 30549<br>B-FAC-X-P5501-010EQ |
| 23 | P5601-010 | TEClot Factor XI | 10x1ml | Coagulation factor xi | W0103020210 / 30551<br>B-FAC-XI-P5601-010A8 |
| 24 | P5701-010 | TEClot Factor XII | 10x1ml | Coagulation factor xii | W0103020211 / 30552<br>B-FAC-XII-P5701-010CJ |

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


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# TEClot PT-S

CE 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 storage[4]
1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 30d at -20°C 6m at -70°C

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

| Prothrombin Time | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 50µl | CP1 | 25µl | CP1 |
| BUF | IBS Buffer | 0µl | P39 | 0µl | P79 |
| CLR | - | 0µl | - | 0µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | - | 0µl | P00 | 0µl | P00 |
| R2 | PT Reagent | 100µl | P25 | 50µl | P46 |

| | A4 | A6 |
|---|---|---|
| Incubation | 0s | |
| Maxtime | 120s | |
| Unit | 251 | |
| Method | Coag | |
| Math | log XY | |
| CT-Mech | No | |
| Deadtime | 7s | |

| | A4 | A6 |
|---|---|---|
| SENS | 2 | |
| POINTS | 4 | |
| MIX | No | |
| Clean | 0 | 0 |
| Multi | 1 | 3 |
| S-Corr | 0% | |
| T-Corr | 30% - 4s | |

**B. Manual Method: Coatron M system**
1. Incubate PT reagent at 37°C for at least 10 minutes
2. Pipette **25 µl of sample** into a test cuvette. Incubate at 37°C for 1-2 minutes.
3. Add **50 µl of PT reagent** (37°C) and simultaneously start test.
4. Record the clotting time in seconds.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

## Expected Results
Typical seconds: 11 – 18 sec
Normal range: 70 - 130% 0.85 – 1.15 INR

However results are influenced by instruments, technique, calibration etc. Each laboratory is recommended to establish its own range on the specific instrument used.

## Standardisation and Calibration
The PT result is expressed as seconds or activity (% Quick) or INR (International Normalised Ratio).

INR results:
were calculated from normal time and ISI value (international sensitivity index). First is obtained by running fresh plasma from a pool of healthy individuals. The ISI value is stated in the LOT specific certificate of analysis.

$$INR = \left(\frac{Patient\ PT}{Normal\ PT}\right)^{ISI}$$

Activity % (Quick) result:
were calcaluted from a calibration curve, which is prepared from reference plasma (e.g. TECAL N) and dilutions in saline solution like 0.9% $NaCl_2$ 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 same 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:
1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfere optical systems

B. Laboratory Techniques
1. Perform tests at 37°C.
2. Use only high purity water.
3. Optimum pH is 7.0-7.5.
4. ISI value is not constant within the first 30 min after reconstitution.
5. 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

1. Quick, A.J., The Hemorrhagic Diseases and the Physiology of Hemostasis. Charles C. Thomas: Springfield, IL. 1942.
2. Quick, A.J., Hemorrhagic Diseases. Lea and Febiger: Philadelphia. 1957.
3. Miale, J.B., Laboratory Medicine-Hematology, 4th Edition. C.V. Mosby: St. Louis. 1972.
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.
5. 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
6. Besselaar A M H P van den. 1991. The significance of the International Normalized Ratio (INR) for oral anticoagulant therapy. H17CC 3; 146153.


Symbol keys

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Expiry date | IVD | In Vitro Diagnostica | | Biological hazard | REF | Catalogue Number | | Reconstitute with dest. water | | Consult accompanying documents |
| | Store at 2-8°C | CE | EU conformity | | Manufacturer | LOT | Lot. Number | | Ready to use | EC REP | Authorized Representative |

# TEClot APTT-S

CE IVD REF **A0300-025, A0300-050, A0320-050, A0320-100**

## Intended Use

This product is intended for determination of Activated Partial Thromboplastin Time (APTT) using silicate as activator. The determination of the APTT is used for the global evaluation of the intrinsic pathway and detecting deficiencies of the intrinsic coagulation factors VIII, IX, XI, XII, and Fletcher Factor as well as for monitoring heparin anticoagulant therapy or other coagulation methods where an APTT reagent is required[1,2]. The APTT reagent in the kit contains phospholipids and silica to ensure a highly consistent and stable product[3]. The APTT reagent is lupus anticoagulant insensitive. Lupus anticoagulant insensitive reagents yield more reliable factor assay results than reagents, which are sensitive to lupus inhibitors[4]. Prolonged clotting times maybe observed in the following situations: deficiency of intrinsic coagulation factors, presence of heparin, in liver diseases, vitamin K Deficiency or other anticoagulants, which affect the intrinsic pathway.

## Contents & Determinations

| Product | TEClot APTT-S Kit-25 | TEClot APTT-S Kit-50 | TEClot APTT-S | TEClot APTT-S |
|---|---|---|---|---|
| Cat.No. | A0300-025 | A0300-050 | A0320-050 | A0320-100 |
| APTT-S Reagent* | 5x5 mL | 5x10 mL | 10x5 mL | 10x10 mL |
| $CaCl_2$ 0.025M** | 5x5 mL | 5x10 mL | - | - |

Determinations

| | | | | |
|---|---|---|---|---|
| Coatron M*** | 1000 Det. | 2000 Det. | 2000 Det. | 4000 Det. |
| Coatron A4 | 500 Det. | 1000 Det. | 1000 Det. | 2000 Det. |
| Coatron A6 | 1000 Det. | 2000 Det. | 2000 Det. | 4000 Det. |

*APTT-S Reagent contains colloidal silicate with phospholipids, buffer and preservatives.
**$CaCl_2$ contains sodium azide.
***Micro method (75µL in total)

## Preparation

Components of kit are ready to use. Allow $CaCl_2$ to prewarm 15 min at 37 °C and mix APTT reagent gently prior usage

## Storage & Stability

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

| | 2-8 °C | 20-25 °C | 37 °C |
|---|---|---|---|
| APTT-S Reagent | 30 days | 8 days | 8 hours |

## Precautions

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

## Specimen collection and storage[5]

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

## Procedure

**A. Automated Method: Coatron A**

| APTT-S | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 50µl | CP1 | 25µl | CP1 |
| BUF | - | 0µl | P00 | 0µl | P00 |
| CLR | - | 0µl | - | 0µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | APTT-S | 50µl | P31 | 25µl | P60 |
| R2 | CaCl 25mM | 50µl | P26 | 25µl | P47 |

| | A4 | A6 |
|---|---|---|
| Incubation | 180s | |
| Maxtime | 180s | |
| Unit | 17 | |
| Method | Coag | |
| Math | - | |
| CT-Mech | No | |
| Deadtime | 17s | |

| | A4 | A6 |
|---|---|---|
| SENS | 1 | |
| POINTS | 0 | |
| MIX | No | |
| Clean | 0 | 0 |
| Multi | 1 | 3 |
| S-Corr | 0% | |
| T-Corr | 15% - 6s | |

**B. Manual Method: Coatron M**

1. Prewarm **$CaCl_2$** (0.025M) at 37°C for at least 10 min
2. Pipette **25 µl of sample** into a test cuvette. Prewarm at 37°C for 1-2 minutes.
3. Add **25 µl APTT-S reagent** and incubate exactly for **3 min** at 37°C.
4. Add **25 µl of $CaCl_2$** (0.025M) and simultaneously start test.
5. Record the clotting time in seconds.

## Expected Results

Typical normal results are 27-42 sec. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

## Quality Control

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

## Limitations

A. Specimen Collection. AVOID:
   1. Use only plastic tubes or siliconised glass.
   2. Delayed mixing of blood with anticoagulant.
   3. Contamination with tissue thromboplastin.
   4. Improper ratio of anticoagulant with blood.
   5. Hemolyzed, icteric or lipemic samples may interfere optical systems

B. Laboratory Techniques
   1. Perform tests at 37°C.
   2. Use only high purity water.
   3. Optimum pH is 7.0-7.5.

## Performance Characteristics

**Typical performance on instrument Coatron M4**

| **Precision:** | CV% (within run) | CV% (inter-runs) |
|---|---|---|
| QC control | < 3,0 | < 5,0 |

**Factor & Heparin sensitivity:**

| | APTT Clotting time ( s) | | |
|---|---|---|---|
| Factor (%) | F VIII | F IX | F XI |
| < 1% | 100 | 80 | 103 |
| 10% | 53 | 52 | 58 |
| 40% | 40 | 39 | 41 |
| 100% | 35 | 35 | 358 |

| Heparin (U/mL) | 0 U/mL | 0,2 U/mL | 0,4 U/mL |
|---|---|---|---|
| APTT clotting time (s) | 35 | 70 | 180 |

These values should be used as guidelines only. Each laboratory should establish factor or heparin sensitivity using its own instruments and techniques.

## Warranty

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

## References


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


Symbols key:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Expiry date | 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 REP | Authorized Representative |

# Calcium Chloride 0,025M

CE 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 $CaCl_2$ 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 REP | Authorized Representative |

# Calcium Chloride 0,025M

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 Hyrogenazid 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 |

# TEClot TT

CE 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 polybrene[1] , normal plasma mixing studies[2] or reptilase assay[3] 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 storage[4]
1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

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

| TT A0401-020 | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 100µl | CP1 | 50µl | CP1 |
| BUF | - | 0µl | P00 | 0µl | P00 |
| CLR | - | 0µl | - | 0µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | - | 0µl | P00 | 0µl | P00 |
| R2 | TT Reagent | 50µl | P27 | 25µl | P50 |

| | A4 | A6 |
|---|---|---|
| Incubation | 0s | |
| Maxtime | 120s | |
| Unit | 3 | |
| Method | Coag | |
| Math | - | |
| CT-Mech | No | |
| Deadtime | 5s | |

| | A4 | A6 |
|---|---|---|
| SENS | 2 | |
| POINTS | - | |
| MIX | No | |
| Clean | 0 | 2 |
| Multi | 1 | 3 |
| S-Corr | 0% | |
| T-Corr | 20% - 3s | |

(Refer to instrument operation manual for detailed instructions)

**B. Manual Method: Coatron M system**

1. Pipette **50 µl of sample** into a test cuvette. Incubate at 37°C for 1-2 minutes.
2. Add **25 µl of TEClot TT** reagent and simultaneously start test.
3. 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 s [6]. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

## Quality Control
TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

## Limitations
A. Specimen Collection. AVOID:
1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfere optical systems
6. Heparin below 1U/mL will not interfere results.

B. Laboratory Techniques
1. Perform tests at 37°C.
2. Use only high purity water.
3. 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 Time[5]. 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 Time[1].

## 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

1. Laposata et al. The Clinical Haemostasis Handbook, Yearbook Medical Publishers Inc., p219, 1989.
2. Thompson, A.R. and Harker, L.A. Manual of Haemostasis and Thrombosis. 3rd Ed., F.A. Davis Co., p62,1983.
3. DeMott, W.R., in: Laboratory Test Handbook, 2nd Ed., Jacobs D.S. et al Eds., Lexi.Comp Inc., p432-433, 1990.
4. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays
5. Gastineau, D.A. et al. Inhibitor of the Thrombin Time in Systemic Amyloidosis: A Common Coagulation Abnormality Blood, 1991, 77: 2637-2640.
6. Lothar Thomas, Labor und Diagnose, 6.Auflage,2005, Page846


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 REP | Authorized Representative |

# TEClot FIB

CE 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 use[2]. Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenaemia (no detectable fibrinogen), hypofibrinogenaemia (<1 mg/ml) and dysfibrinogenaemia (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)

1. 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
2. IBS Buffer: Ready to use. Contains Imidazole buffered saline
3. TECal Normal: Reconstitute with 1 mL purified water. Contains citrated human plasma.
4. TEControl A: Reconstitute with 1 mL purified water. Contains citrated human plasma.

Swirl gently after reconstitution and allow standing for 15 minutes at room temperature. Mix well before use. Do not shake.

## Storage & Stability

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

| | | | |
|---|---|---|---|
| Thrombin Reagent* | 2-8 °C | 15-25 °C | 37 °C |
| | 12 days | 5 days | 24 hours |
| TEControl or Plasma | 2-8 °C | 15-25 °C | -20 °C |
| | 8 hours | 4 hours | 30 days |

* Reagent must be protected from UV-light and evaporation

## Precautions

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

## Specimen collection and storage[3]

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

## Procedure

**A. Automated Method. Coatron A**

| Fibrinogen | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 10µl | CP1 | 10µl | CP1 |
| BUF | IBS Buffer | 90µl | P39 | 90µl | P79 |
| CLR | - | 0µl | - | 0µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | - | 0µl | P00 | 0µl | P00 |
| R2 | Fibrinogen | 50µl | P29 | 50µl | P49 |

| | A4 | A6 |
|---|---|---|
| Incubation | 0s | |
| Maxtime | 120s | |
| Unit | 769 | |
| Method | Coag | |
| Math | log XY | |
| CT-Mech | Yes | |
| Deadtime | 3s | |

| | A4 | A6 |
|---|---|---|
| SENS | 0 | |
| POINTS | 4 | |
| MIX | No | |
| Clean | 1 | 3 |
| Multi | 1 | 1 |
| S-Corr | 0% | |
| 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

A. Specimen Collection. AVOID:
   1. Use only plastic tubes or siliconised glass.
   2. Delayed mixing of blood with anticoagulant.
   3. Contamination with tissue thromboplastin.
   4. Improper ratio of anticoagulant with blood.
   5. Hemolyzed, icteric or lipemic samples may interfer optical systems

B. Laboratory Techniques
   1. Perform tests at 37°C.
   2. Use only high purity water.
   3. Optimum pH is 7.0-7.5.

## Performance Characteristics

| **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


1. Clauss, A., Gerinnungsphysiologische Schnellmethode zur bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
2. Shaw, T.S.,Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
3. 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.
4. Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37) : 37-48.
5. Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6) : 196-201.


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 REP | Authorized Representative |

# TEClot FIB

IVD REF **A0501-010, A0501-025, A0511-020, A0511-050**

## Verwendungszweck

TEClot FIB wird zur quantitativen Bestimmung von Fibrinogen im menschlichen Plasma nach einer von Clauss[1] entwickelten Methode verwendet. Der Fibrinogenpegel kann auf Grund von Entzündungen, Schwangerschaft und dem Gebrauch von Ovulationshemmern ansteigen[2]. Geringere Konzentrationen können bei verschiedenen Krankheiten wie Leberversagen und DIC auftreten. Angeborene Defizite beinhalten Afibrinogenämie (kein auffindbares Fibrinogen), Hypofibrigonämie (<1mg/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

| | | | | |
|---|---|---|---|---|
| Coatron M* | 400 Det. | 1000 Det. | 800 Det. | 2000 Det. |
| Coatron A4 | 200 Det. | 500 Det. | 400 Det. | 1000 Det. |
| Coatron A6 | 200 Det. | 500 Det. | 400 Det. | 1000 Det. |

*Mikromethode (75µL insgesamt)

1. 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
2. IBS Puffer: gebrauchsfertig, 125ml
   Enthält gepufferte Natriumchlorid Lösung, pH 7,3-7,4
3. TECal Normal: Mit 1ml hochreinem Wasser anlösen
   Enthält mit Zitrat versetztes menschliches Plasma.
4. TEControl A: Mit 1ml hochreinem Wasser anlösen
   Enthält mit Zitrat versetztes menschliches Plasma.

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

## Lagerung und Stabilität

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

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

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

## Vorsichtsmaßnahme

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

## Probenentnahme und Lagerung [3]

1. Venöses Blut mittels Venenpunktur unter sauberen Bedingungen entnehmen.
2. Sofort 9 Teile Blut mit einem Teil 3,2% Natriumzitrat (0,105M) gut mischen.
3. Probe bei 1500g 10 Minuten lang zentrifugieren (Thrombozyten <10000µl)
4. Plasma nach der Zentrifugierung entfernen und in einem Röhrchen aus Plastik oder silikonisierten Glas aufbewahren.
5. Plasma innerhalb von 4 Stunden verwenden, andernfalls gefroren lagern und kurz vor Gebrauch auftauen.

## Verfahren

**A. Automatenmethode: Coatron A**

| Fibrinogen | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 10µl | CP1 | 10µl | CP1 |
| BUF | IBS Buffer | 90µl | P39 | 90µl | P79 |
| CLR | - | 0µl | - | 0µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | - | 0µl | P00 | 0µl | P00 |
| R2 | Fibrinogen | 50µl | P29 | 50µl | P49 |

| | A4 | A6 |
|---|---|---|
| Incubation | 0s | |
| Maxtime | 120s | |
| Unit | 769 | |
| Method | Coag | |
| Math | log XY | |
| CT-Mech | Yes | |
| Deadtime | 3s | |

| | A4 | A6 |
|---|---|---|
| SENS | 0 | |
| POINTS | 4 | |
| MIX | No | |
| Clean | 1 | 3 |
| Multi | 1 | 1 |
| S-Corr | 0% | |
| T-Corr | 0% | |

**B. Manuelle Methode: Coatron M**

1. 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 |

2. 50µl verdünntes Standard- oder Patientenplasma (1:10) in eine Küvette pipettieren. Bei 37°C für 1-2 Minuten erwärmen
3. 25µl Thrombinreagenz hinzufügen und gleichzeitig Test starten.

Wenn Sie ein anderes Gerät verwenden, lesen Sie bitte für genauere Informationen die entsprechende Geräteanleitung.

## Kalibrierung

TECal Normal oder anderes kommerzielles Standardplasma, mit bekanntem Fibrinogengehalt, sollte als Referenz (200-300 mg/dl) verwendet werden. Geben Sie die Gerinnungszeit jeder FIB Standard Lösung auf der Y- Achse gegen die FIB Konzentration (mg/dl) auf der X- Achse an. Verwenden Sie Millimeterpapier. Die Reihe der besten Ergebnisse sollte durch lineare Regressionsanalyse bestimmt werden. Fibrinogen in den Plasmaproben kann durch Interpolation der Kalibrierungskurve bestimmt werden.

## Erwartete Ergebnisse

Typische normale Ergebnisse sind 180-450mg/dl[4,5]. Die Ergebnisse sind jedoch von der Methode, wie die Gerinnungszeit bestimmt wird, abhängig und können von Labor zu Labor variieren. Jedem Labor wird empfohlen, seinen
eigenen normalen Ergebnisbereich auf dem verwendeten Instrument zu erstellen.

## Qualitätskontrolle

TEControl oder anderes kommerzielles Kontrollplasma sollte, um eine gute Qualität sicherzustellen, in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. TEControl kann einmalig wieder eingefroren werden. Hierfür 120-150µL in einem verschließbaren polypropylen Gefäß bei -20°C aufbewahren und innerhalb der nächsten 30 Tage verwenden.

## Beschränkungen

A. Probenvorbereitung. Achten Sie auf:
1. nur Plastikröhrchen oder silikonisiertes Glas verwenden
2. verzögertes Mischen von Blut mit Antikoagulanz vermeiden
3. Kontaminierung mit Gewebethromboplastin vermeiden
4. falsches Verhältnis von Antikoagulanz 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

## Leistungsdaten

| **Präzision:** | VK% (Einzellauf) | VK% (Mehrfachlauf) |
|---|---|---|
| Normale Kontrolle | < 5.0 | < 5.0 |
| Abnormale Kontrolle | < 5.0 | < 10.0 |

(Typische Leistung beim Gerät Coatron M4)

## Garantie

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

## Referenzen


1. Clauss, A., Gerinnungsphysiologische Schnellmethode zur bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
2. Shaw, T.S.,Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
3. 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.
4. Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37) : 37-48.
5. Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6) : 196-201.


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 |

## Revisions-Übersicht:

| Rev. | am | Änderung durch | Gültig für | Freigabe am | Freigabe durch |
|---|---|---|---|---|---|
| 1 | 5.4.11 | WG | Technoclone FIB | | |
| | Beschreibung: | New box insert for Technoclone FIB. | | | |
| 2 | 21.12.11 | CB | Technoclone FIB | 21.12.11 | CH |
| | Beschreibung: | Neue Stabilitätsangaben. Die Vorgaben wurden dem Technoclone Stability Test Report „TC6E0C.01“ vom 5.5.2010 entnommen. | | | |
| 3 | 11.11.13 | CB | Technoclone FIB | | |
| | Beschreibung: | - Protokoll für A4+A6<br>- Stabilitätsdaten neu | | | |
| 4 | 16.10.17 | AR | Technoclone FIB | 16.10.17 | CH |
| | Beschreibung: | Technoclone Puffer (A0591-090) wird ersetzt durch IBS (A0590-125)<br>(wegen deutlicher Messunterschiede bei Coatron A und X Serie)<br>Werteermittlung für das CoA erfolgt ebenso mit IBS (A0590-125) | | | |
| 5 | 23.01.18 | VG | Technoclone FIB | 23.01.18 | VG |
| | Beschreibung: | Neue Stabilitätsangaben von Technoclone vom Thrombin Reagent. | | | |

# IBS Buffer

CE IVD REF ***A0590-125***

### Intended Use
The IBS Buffer solution is optimally formulated for use on Coagulation Analyzers. Use in accordance with the recommended Operators Manuals for installing and replacing Owrens Veronal Buffer (OVB). The IBS can be used as the diluent for preparing plasma dilutions in the performance of Fibrinogen determinations and Coagulation Factor Assays with all manual, mechanical, or photo-optical means of clot detection. Follow Reagent manufacturer's recommended procedures for preparation of plasma dilutions using Imidazole Buffered Saline.

### Contents & Determinations

| | |
|---|---|
| Product | IBS Buffer |
| Cat.No. | A0590-125 |
| IBS Buffer | 1x125 mL |

### Preparation
IBS: pH 7.3 - 7.4, liquid
Ready to use.

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

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

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

Symbols key:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Expiry date | 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 REP | Authorized Representative |

# IBS Buffer

CE IVD REF *A0590-125*

### Verwendungszweck
Die IBS Pufferlösung (Imidazole Buffered Saline) wird für die Verdünnung von Plasma verwendet werden, wie es z.B. bei der koagulometrischen Bestimmung von Fibrinogen, Einzelfaktoren oder auch Verdünnungsreihen für die Methoden Kalibrierung notwendig ist.

### Inhalte und Bestimmungen

| | |
|---|---|
| Produkt | IBS Puffer |
| Kat.Nr. | A0590-125 |
| IBS Buffer | 1x125 mL |

### Vorbereitung
IBS: pH 7.3 - 7.4, flüssig
Gebrauchsfertig

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

### Vorsichtsmaßnahmen
Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Bestandteile gemäß lokaler Vorschriften für infektiöse Materialien entsorgen.

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

# Blue D-Dimer LC

CE IVD REF D2020-005

*In-Vitro-Diagnostic reagent for professional use*

## Intended Use
Immunoturbidimetric reagent for the quantitative determination of D-Dimer concentration in human plasma on optical Coagulometer at 400-600nm.

Fibrin fragments containing D-dimer antigen is always present in plasma as a result of plasmin degradation of cross-linked fibrin. After an injury, or when suffering from conditions associated with increased haemostatic activity, there is an increase in plasma D-dimer concentration. D-dimer determination has become a common aid in the diagnosis of thrombosis. Elevated levels of D-dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC) [1-4]. A negative D-dimer test result from a patient with a suspected thrombotic disorder has a high negative predictive value.

## Contents & Determinations

| | |
|---|---|
| Product | Blue D-Dimer LC (Kit) |
| REF. | D2020-005 |
| Latex | 1x5 mL , containing BoviPolystyrene particles, coated with monoclonal antibodies, suspended in buffer with stabilisers and preservatives |
| Reaction Buffer | 1x7 mL, containing buffer, Heterophilic Blocking Reagent (HBR), and preservatives. |
| Determinations | 100 Det (on Coatron-X) |

Recommended additional material (not included in package)

| | |
|---|---|
| Calibration | P8200-005 TECal DD, 5 x 1mL<br>or plasma with known high level of D-Dimer.<br>Dilution buffer to prepare calibrator levels like:<br>A0593-035 Dilution Buffer, 5 x 7mL or<br>A0590-125 IBS Buffer, 1 x 125mL or<br>Normal saline (NaCl 0.9%) or<br>Phosphate buffered saline (PBS) |
| Quality Control | P6001-010 TEControl N, 10 x 1mL<br>P6101-010 TEControl A, 10 x 1mL |

## Preparation
**Latex**: liquid, ready to use. Swirl gently before use.
**Reaction Buffer**: liquid, ready to use.

## Storage & Stability
Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Do not freeze. Opened reagent stored in original vial

| | | | |
|---|---|---|---|
| Latex & Buffer | 2-8 °C | 20-25 °C | 37°C |
| in closed condition | 8 weeks | 4 weeks | 4 weeks |
| on-board - open condition | 7 days | 1 day | 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, material should be considered as potentially infectious.

## Specimen collection and storage[4]
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 siliconized glass tube.
5. Use plasma within 8 hours, otherwise store frozen and thaw just prior to use.

## Procedure
**A. Coatron A Method**
See application book of device
**B. Coatron X Method**
The performing is demonstrated on a video, which you can download on our website.

| | |
|---|---|
| Pipette to empty cuvette | **25µL plasma** |
| Add | **50µL Reaction Buffer** |
| Incubate at 37°C | **1-2min** |
| Add | **50µL prewarmed Latex and mix well.** |
| | ***The device measures the rate of the Ag+Ab reaction between 20 –180 s.*** |

**Laboratory techniques and requirements**
1. Mix up & down at least 10x with pipette directly after adding latex reagent to obtain accurate results. Avoid air bubbles during mixing. Stop mixing latest 10sec after start. Dispose yellow tip after mixing.
2. Do not touch cuvette during measurement.
3. Avoid very bright external UV light sources like sunlight will interfere result

## Calibration Coatron X
A minimum of 3 calibration points is required. Prepare the concentrations according to table below, run in duplicates on device and transfer manually the results to its calibration curve.

| | Concentration | Calibrator | Dilution Buffer |
|---|---|---|---|
| Cal. 1 | ~ 3200 ng/mL | 200 µL TECal DD | - |
| Cal. 2 | ~ 1600 ng/mL | 200 µL TECal DD | 200 µL |
| Cal. 3 | 1 ng/mL | This point is not measured, but just entered as 1ng=0.001E | |

A recalibration is suggested at least when control plasmas are not within the acceptable range and each time a new batch of reagent is used.

## Expected Results
D-Dimer results can be reported in D-dimer units (DDU) or Fibrinogen Equivalent Units (FEU). 1 FEU is equal to 2.50 DDU. TECO is using DDU in certificates. Results below 200 ng/mL DDU can be regarded as D-dimer negative and are typical for normal healthy normal subjects[4-6]. Elevated levels are observed in causes of PE, DVT (deep venous thrombosis), DIC, trauma[7], pregnancy and with age[8-9].

As there is no internationally established standard for D- dimer, the concentration of D-dimer in any given specimen may differ when determined using D-dimer assays from different manufacturers. Thus, each laboratory should establish its own reference intervals or cut-off levels or control ranges.

## Quality Control
TEControl N & 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).

## Limitations

| Interfering substances | Tolerance Coatron X | Tolerance Sysmex CS Series |
|---|---|---|
| Bilirubin | Up to 20 mg/dL | Up to 12 mg/dL |
| Haemoglobin | Up to 400 mg/dL | Up to 100 mg/dL |
| Triglycerides | Up to 150 mg/dL | Up to 160 mg/dL |
| Heparin (UFH): | Up to 3 U/mL | Up to 3 U/mL |

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain anti-mouse antibodies (HAMA), which may cause over-estimation of D-dimer values. The presence of rheumatoid factor may also result in falsely elevated D-dimer values.

## Performance Characteristics
(on Coatron X)

**Reportable range:** 125 -3500 ng/mL DDU
Results below should be considered as "<125".
Results above should be re-assayed 1:4 diluted with Saline Solution.

**Precision:** 300 ng/mL DDU CV. = 8.2% (within run)
1000 ng/ml DDU CV. = 2.3% (within run)
Appropriate mixing is required to achieve good accuracy.

**Hook effect:** 75000 ng/mL DDU.
Samples with above DD levels may be reported as false negatives.

**Diagnostic performance:**

| CUT-OFF | Sensitivity | Specificity | NPV | PPV |
|---|---|---|---|---|
| DDU=200ng/mL<br>FEU=500ng/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. HEIT, John A., et al. Determinants of plasma fibrin D-dimer sensitivity for acute pulmonary embolism as defined by pulmonary angiography. Archives of Pathology and Laboratory Medicine, 1999, 123.3:235-240.
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| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 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 REP | Authorized Representative |

# TEChrom AT liquid *(anti-Xa)*

CE IVD REF *C1010-020*

## Intended Use

The TEChrom ATIII (anti-Xa) liquid kit is intended for the quantitative determination of Antithrombin (AT) activity in human citrated plasma by chromogenic assay.

AT is a major inhibitor of blood coagulation, acting to inhibit plasma serine proteases including factors IXa, Xa, XIa, and thrombin. The rate of the inhibition is significantly increased in the presence of heparin. AT deficiency may be congenital or acquired and is associated with an increased risk for thrombosis[1-3]. Deficiencies may occur in liver disease, disseminated intravascular coagulation (DIC), septicaemia, pulmonary embolism, nephrotic syndrome, stroke, and thrombophlebitis.

Most functional assays for AT rely on the ability of plasma to inactivate thrombin in the presence of heparin, such as the assay described by Odegard *et al*[4]. More recently, it has been shown that a method based on the ability of plasma to inhibit factor Xa in the presence of heparin may be more accurate, since it eliminates interference due to heparin cofactor II[5]which does not inhibit factor Xa[6].

Antithrombin activity is determined with two stage chromogenic method:
1. Factor Xa is added to a plasma dilution containing AT in the presence of excess heparin and Calcium.
2. A factor Xa-specific chromogenic substrate is added and the rate of hydrolyis is monitored with a photometer at 405nm. The release of pNA is depending on the residual factor Xa and inversely proportional to the AT concentration.

## Contents & Preparation

| | |
|---|---|
| Product | TEChrom AT(anti-Xa) liquid |
| Cat.No. | C1010-020 |
| Factor Xa Substrate | 3 x 3mL |
| Factor Xa Reagent | 6 x 6mL |
| IBS Buffer | 1 x 125mL |
| TECal Normal | 1 x 1mL |
| TEControl A Plus | 1 x 1mL |

Determinations:

| Coatron M | Coatron A4 | Coatron A6 |
|---|---|---|
| 360 | 225 | 360 |

1. Factor Xa Reagent:
   Bovine factor Xa, 10nKat/mL, in Tris buffer pH8.2, containing heparin, stabilizers and preservatives. Ready to use.
2. Factor Xa Substrate
   Chromogenic Fxa substrate in water medium containing detergent and preservatives. Ready to use.
3. IBS Buffer: Ready to use.
4. TECal Normal & TEControl A Plus:
   Contains citrated human plasma. Reconstitute with 1 mL distilled water.

Swirl gently after reconstitution and allow standing for 15 minutes at room temperature. Mix well before use. Do not shake

**Further materials required:**

- Coagulation analyzer ( Coatron A4 )
- Calibrated pipettes

## Storage & Stability

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

| | 2-8 °C | 12-15 °C | 37°C |
|---|---|---|---|
| Factor Xa Reagent | 1 month | 48 hours | 4hours |
| Factor Xa Substrate | 1 month | 48 hours | 4hours |
| IBS Buffer | See expiry date | | |
| TECal Normal | 8 hours | 4 hours | 1 hour |
| TEContol A Plus | 8 hours | 4 hours | 1 hour |

## 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.

Some components of this kit contain sodium azide as a preservative. To prevent the build-up of potentially explosive metallic azides in metal plumbing, flush sinks with copious amounts of water and decontaminate regularly with sodium hydroxide solution.

## Specimen collection and storage[7]

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

## Procedure

**A. Automated Method: Coatron A**

| AT Liquid (C1010) | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 10µl | CP1 | 10µl | CP1 |
| BUF | IBS Buffer | 90µl | P39 | 90µl | P79 |
| CLR | Clear | 50µl | - | 70µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | FXa reagent | 150µl | P32 | 90µl | P64 |
| R2 | FXa substrate | 40µl | P28 | 24µl | P57 |

| | A4 | A6 |
|---|---|---|
| Incubation | 120s | |
| Maxtime | 90s | |
| Unit | 34819 | |
| Method | Chrom | |
| Math | Lin | |
| CT-Mech | No | |
| Deadtime | 9s | |

| | A4 | A6 |
|---|---|---|
| SENS | 0 | |
| Point | 3 | |
| MIX | No | |
| Clean | 1 | 3 |
| Multi | 0 | 3 |
| S-Corr | 0% | |
| T-Corr | 0% | |

**B. Manual Method: Coatron M**

System Setup:

| | | | |
|---|---|---|---|
| Method: KINETIC | Unit: % | OD-corr: 0% (100) | Coag-corr:0% (100) |

(Refer to instrument operation manual for detailed instructions)

Preparation of Standard, Control and Patient Dilutions

| STD(%ATIII) | Plasma | IBS Buffer |
|---|---|---|
| 100% | 50µL Standard | 500µL |
| 50% | 200µL 100% STD | 200µL |
| 25% | 200µL 50% STD | 200µL |
| 12.5% | 200µL 25% STD | 200µL |
| Patient or Control | 50µL Plasma | 500µL |

1. Pipette **25 µl sample 1:11 diluted** into cuvette.
2. Add **100µl Factor Xa Reagent,** mix and incubate at 37°C for 2 minutes.
3. Add **25µl Factor Xa Substrate** and simultaneously start test.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

## Expected Results

Typical normal results are 75 – 125%. However results can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.
Plasma activity levels of 30-60% can be observed in patients with hereditary AT deficiency. Several clinical conditions associated with acquired AT deficiency include: liver disease, DIC, nephrotic syndrome, pulmonary embolism, stroke, and thrombophlebitis. In addition, oral contraceptive use may lead to reduced AT levels [2].

## Quality Control

TEControl or other commercially 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

## Specificity & Interferences

TEChrom AT (anti-Xa) liquid, which is based upon the use of FXa, is not influenced by Heparin Cofactor II activity. Furthermore, no influence is caused by UF and LMW heparin up to 4.2 U/mL, by bilirubin up to 43 mg/dL, by triglycerides up to 520 mg/dL and by hemoglobin up to 140 mg/dL.

## Performance Characteristics

**Typical performance on instrument Coatron A4**

| **Precision:** | CV% (within run) | CV% (inter-runs) |
|---|---|---|
| Normal control | < 5,0 | < 10,0 |
| Abnormal control | < 5,0 | < 10,0 |
| Linearity | 15 – 125% | 15 – 125% |

## Linearity

This assay is designed to give a linear standard curve for AT levels between 15% and 125%. Samples over 125% should be diluted in IBS Buffer and re-assayed.

# TEChrom AT liquid *(anti-Xa)*

CE IVD REF *C1010-020*

**Limitations**

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

A. Specimen Collection. AVOID:
1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfer optical systems

B. Laboratory Techniques
1. Perform tests at 37°C.
2. Use only high purity water.
3. Optimum pH is 7.0-7.5.

**Warranty**

This product is warranted to perform in accordance with its labeling 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**


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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 REP | Authorized Representative |



TECO GmbH, Dieselstr. 1, 84088 Neufahrn NB Germany

# TEChrom AT liquid *(anti-Xa)*

CE IVD REF *C1010-020*

## Verwendungszweck
TEChrom AT (anti-Xa) flüssig dient der quantitativen Bestimmung von Antithrombin(AT)-Aktivität in humanem Zitratplasma mittels chromogenem Ansatz.

AT ist ein wichtiger Blutgerinnungsinhibitor, dessen Wirksamkeit in der Blockierung von Plasma-Serinproteasen einschließlich der Faktoren IXa, Xa, Xia und Thrombin besteht. Die Inhibitionsrate wird durch Vorhandensein von Heparin signifikant verstärkt. ATIII Defizit kann vererbt oder erworben werden und wird mit einem erhöhten Thromboserisiko assoziiert[1-3]. Defizite können bei Lebererkrankungen, DIC, Blutvergiftung, Lungenembolie, nephrotischem Syndrom, Schlaganfall und Thrombophlebitis auftreten[2-3].

Die meisten funktionellen Ansätze für AT basieren auf der Fähigkeit von Plasma, Thrombin in Anwesenheit von Heparin zu inaktivieren, so z.B. der von Odegard et al [4] beschriebene Ansatz. Vor kurzem zeigte sich, dass eine Methode, die auf der Fähigkeit des Plasmas basiert, den Faktor Xa in Anwesenheit von Heparin zu blockieren, möglicherweise genauer ist, da sie die Interferenz des Heparin-Kofaktors II eliminiert [5], welcher Faktor Xa nicht blockiert.

Die Antithrombinaktivität wird mit einer zweistufigen chromogenen Methode bestimmt:
1. Faktor Xa wird einer Plasmaverdünnung mit AT in Gegenwart von hohen Menge Heparin und Kalzium zugefügt.
2. Ein Faktor-Xa spezifisches Chromogensubstrat wird zugefügt und der Anteil der Hydrolyse mittels eines Photometers mit 405nm angezeigt. Die Freisetzung von pNA hängt vom verbleibenden Faktor Xa ab und ist umgekehrt proportional zur ATIII Konzentration.

## Inhalt und Bestimmungen

| | |
|---|---|
| Produkt | TEChrom AT(anti-Xa) liquid |
| Kat.Nr. | C1010-020 |
| Faktor Xa Substrat | 3 x 3mL |
| Faktor Xa Reagenz | 6 x 6mL |
| IBS Puffer | 1 x 125mL |
| TECal Normal | 1 x 1mL |
| TEControl A Plus | 1 x 1mL |

Bestimmungen:

| Coatron M | Coatron A4 | Coatron A6 |
|---|---|---|
| 360 | 225 | 360 |

1. Faktor Xa Reagenz:
   Rinderfaktor Xa, 10nKat/mL, in Tris Puffer pH8.2, enthält Heparin, Stabilisatoren und Konservierungsmittel. Gebrauchsfertig.
2. Faktor Xa Substrat
   Chromogenes FXa Substrat in Wasser, enthält Reinigungszusatz und Konservierungsmittel. Gebrauchsfertig.
3. IBS Puffer: Gebrauchsfertig.
4. TECal Normal & TEControl A Plus:
   Enthält zitriertes Humanplasma. Anlösen mit 1 mL destilliertem Wasser.

Nach Anlösen sorgfältig verwirbeln und 15 Minuten lang bei Raumtemperatur stehen lassen. Vor Gebrauch gut mischen. Nicht schütteln.

**Weiteres benötigtes Material:**
- Blutgerinnungsmessgerät ( Coatron A4 )
- Kalibrierte Pipetten

## Lagerung und Stabilität
Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Fläschchenetikett angegebenen Datum haltbar.

| | 2-8 °C | 12-15 °C | 37°C |
|---|---|---|---|
| Faktor Xa Reagenz | 1 Monat | 48 Stunden | 4 Stunden |
| Faktor Xa Substrat | 1 Monat | 48 Stunden | 4 Stunden |
| IBS Puffer | Siehe Verfallsdatum | | |
| TECal Normal | 8 Stunden | 4 Stunden | 1 Stunde |
| TEContol A Plus | 8 Stunden | 4 Stunden | 1 Stunde |

## Vorsichtsmaßnahmen
Haut- und Augenkontakt vermeiden. Schutzkleidung tragen. Bestandteile gemäß örtlichen Bestimmungen für infektuöses Material entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut als potentiell infektiös angesehen werden.

Einige Komponenten dieses Kits enthalten Natriumazid als Konservierungsmittel. Um Explosionen von metallischen Aziden in Metallrohren vorzubeugen, Abflüsse mit viel Wasser spülen und regelmäßig mit Natronlauge dekontaminieren.

## Probenentnahme und Lagerung[7]
1. Unter sauberen Bedingungen venöses Blut durch Venenpunktur entnehmen
2. Sofort neun Teile Blut mit einem Teil 3,2% Natriumzitrat (0.105M) mischen
3. Probe bei 1500g für 10 Minuten zentrifugieren (Thrombozyten < 10000/µl)
4. Plasma nach Zentrifugierung entnehmen und in einem Röhrchen aus Kunststoff oder silikonisiertem Glas aufbewahren.
5. Plasma innerhalb von 4 Stunden verwenden; andernfalls tiefgekühlt aufbewahren und unmittelbar vor Gebrauch auftauen.

Stabilität des Plasmas:

| 18-26°C | 2-8°C | -20°C | -70°C |
|---|---|---|---|
| 4 Stunden | 8 Stunden | 14 Tage | 6 Monate |

## Verfahren
**A. Automaten Methode: Coatron A**

| AT Liquid (C1010) | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 10µl | CP1 | 10µl | CP1 |
| BUF | IBS Buffer | 90µl | P39 | 90µl | P79 |
| CLR | Clear | 50µl | - | 70µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | FXa reagent | 150µl | P32 | 90µl | P64 |
| R2 | FXa substrate | 40µl | P28 | 24µl | P57 |

| | A4 | A6 |
|---|---|---|
| Incubation | 120s | |
| Maxtime | 90s | |
| Unit | 34819 | |
| Method | Chrom | |
| Math | Lin | |
| CT-Mech | No | |
| Deadtime | 9s | |

| | A4 | A6 |
|---|---|---|
| SENS | 0 | |
| POINTS | 3 | |
| MIX | No | |
| Clean | 1 | 3 |
| Multi | 0 | 3 |
| S-Corr | 0% | |
| T-Corr | 0% | |

**B. Manuelle Methode: Coatron M**

System Setup:

| Method: KINETIC | Unit: % | OD-corr: 0% (100) | Coag-corr: 0% (100) |
|---|---|---|---|

(Bedienungsanleitung des Gerätes beachten)

Herstellung von Standard, Kontrolle und Patientenverdünnungen

| STD(%ATIII) | Plasma | IBS Puffer |
|---|---|---|
| 100% | 50µL Standard | 500µL |
| 50% | 200µL 100% STD | 200µL |
| 25% | 200µL 50% STD | 200µL |
| 12.5% | 200µL 25% STD | 200µL |
| Patient oder Kontrolle | 50µL Plasma | 350µL |

1. **25 µl Probe 1:11 verdünnt** in Követte pipettieren.
2. **100µl Faktor Xa Reagenz** zugeben, mischen und bei 37°C 2min lang inkubieren..
3. **25µl Faktor Xa Substrat** zugeben und gleichzeitig Test starten.

Für andere Geräte bitte die entsprechende Geräteanleitung beachten.

## Erwartete Ergebnisse
Typische Normalwerte sind 75 – 125%. Die Ergebnisse sind jedoch von der verwendeten Methode zur Bestimmung der Blutgerinnung abhängig und können von Labor zu Labor variieren. Jedem Labor wird empfohlen, mit den verwendeten Geräten einen eigenen normalen Ergebnisbereich festzulegen.
Plasma-Aktivitätswerte von 30-60% können bei Patienten mit angeborener AT-Defizienz beobachtet werden. Verschiedene klinische Zustände sind mit erworbener ATIII-Defizienz verbunden wie z.B. Lebererkrankung, DIC, nephrotisches Syndrom, Lungenembolie, Schlaganfall und Thrombophlebitis. Darüber hinaus kann die Einnahme von Empfängnisverhütungsmitteln zu reduzierten AT-Werten[2] führen.

## Qualitätskontrolle
TEControl oder anderes kommerzielles Kontrollplasma sollte, um eine gute Qualität sicherzustellen, in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden.

TEControl kann einmalig wieder eingefroren werden. Hierfür 120-150µL in einem verschließbaren polypropylen Gefäß bei -20°C aufbewahren und innerhalb der nächsten 30 Tage verwenden

## Beschränkungen
A. Probenvorbereitung. Achten Sie auf:
   1. nur Plastikröhrchen oder silikonisiertes Glas verwenden
   2. verzögertes Mischen von Blut mit Antikoagulanz vermeiden
   3. Kontaminierung mit Gewebethromboplastin vermeiden
   4. falsches Verhältnis von Antikoagulanz 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

# TEChrom AT liquid *(anti-Xa)*

CE IVD REF *C1010-020*

### Leistungsdaten

**Typische Leistungsdaten bei Gerät Coatron A4**

| **Präzision:** | VK% (Einzellauf) | VK% (Mehrfachlauf) |
|---|---|---|
| Normalkontrolle | < 5,0 | < 10,0 |
| Abnormale Kontrolle | < 5,0 | < 10,0 |
| Linearität | 15 - 125% | 15 – 125% |

### Sensitivität

Dieser Ansatz wurde entwickelt für die Erstellung einer linearen Standardkurve für AT Level zwischen 15% und 125%. Proben über 125% sollten mit IBS Puffer verdünnt und neu angesetzt werden.

### Spezifität & Interferenzen

TEChrom AT (anti-Xa) flüssig, welches auf dem Gebrauch von FXa basiert, wird nicht durch Heparin Kofaktor II Aktivität beeinflusst. Darüber hinaus wird kein Einfluss ausgeübt durch UF und LMW Heparin bis zu 4.2 U/mL, durch Bilirubin bis zu 43 mg/dL, durch Triglyzeride bis zu 520 mg/dL und durch Hämoglobin bis zu 140 mg/dL.

### 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.

### Referenzen


1. Hirsh, J. et al: 'Congenital antithrombin III deficiency. Incidence and clinical features.' Am J. Med., 1989, 87 (suppl. 3B) 34S-38S.
2. Panicucci, F. et al: 'Antithrombin III, heparin cofactor and antifactor Xa in relation to age, sex and pathological condition.' Haemostasis, 1981; 9: 297-302.
3. Conlan, M.G. et al: 'Antithrombin: Antithrombin III: Associations with age, race, sex and cardiovascular disease risk factors.' Thromb. Haemost., 1994; 72(4) 551-556.
4. Odegard, O.R. et al: 'Heparin cofactor activity measured with an amidolytic method.' Thromb. Res., 1975; 6: 287-294.
5. Demers, C. et al: 'An antithrombin III assay based on factor Xa inhibition provides a more reliable test to identify congenital antithrombin III deficiency than an assay based on thrombin inhibition.' Thromb. Haemost., 1993; 69: 231-235.
6. Tolefsen, D.M., Blank, M.K.: 'Detection of a new heparin-dependent inhibitor of thrombin in human plasma.' J. Clin. Invest., 1981; 68: 589-596.
7. 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.


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 |

# TEChrom AT liquid *(anti-Xa)*

CE IVD REF *C1010-020*

## Revisions-Übersicht:

| Rev. | am | Änderung durch | Gültig für | Freigabe am | Freigabe durch |
|---|---|---|---|---|---|
| 1 | | CB | Medirox AT | 21.01.09 | CH |
| | Beschreibung: | Initiale Version erstellt (CB)<br>Format- und Fehlerkorrekturen (CH) | | | |
| 2 | 22.1.2009 | Wendy | Medirox AT | 22.01.09 | CH |
| | Beschreibung: | System-Setup für manuelle Methode eingefügt | | | |
| 3 | 8.7.2009 | CB | Medirox AT | 27.08.09 | CH |
| | Beschreibung: | - Sprachneutrale Kopf + Fusszeile<br>- Deutscher Text integriert<br>- Methode M4 jetzt 1:11 statt 1:8 plasmaverdünnung<br>- Linearität jetzt 15-125 statt 15-125%<br>- Kapitel Limitation: bilirubin entfernt + siliconisiertes glas<br>- Empfehlung für Wiedereinfrieren der Kontrollen ( Kap. „Qualitätskontrolle“) | | | |
| 4 | 22.4.2010 | WG | Medirox AT | 3.5.2010 | CB |
| | Beschreibung: | -Kopfzeile/Fußzeile 0,5/0,0cm Abstand<br>- Text ergänzt: „Symbols Key“<br>- Probenentnahme jetzt wie Geräte Manual<br>- Limitation: Hinweis auf lipemisch,icterisch oder hemolytisch | | | |
| 5 | 11.11.2013 | CB | Medirox AT | | CB |
| | Beschreibung: | -Protokoll für A4+A6 | | | |

# TEControl N

CE IVD REF **P6001-010**

## Intended Use
Use as a normal control for following coagulation tests:

**PT, APTT, Thrombintime, 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 | 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 REP | Authorized Representative |

# TEControl N

CE | IVD | REF | P6001-010

## Verwendungszweck
Als normale Kontrolle für folgende Gerinnungstests verwenden:

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

## Inhalt
10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

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

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

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

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

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

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

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

## Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

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

# TEControl A

CE IVD REF **P6101-010**

## Intended Use
Use as an abnormal control for following coagulation tests:

**PT, APTT, Thrombintime, 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 | 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 REP | Authorized Representative |

# TEControl A

CE 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 | 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 |

# TECal N

IVD REF P8001-005

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

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

## Contents
5 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 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 | 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 REP | Authorized Representative |

# TECal N

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 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 |

# 21 500 01 / 21 500 00 / 21 500 09
# Rinse Solution / Clean B

## Information of Use
This solution is a general laboratory article for a wide range of uses in laboratories. It is also suitable for use in in vitro diagnostic tests.

The Solution is ready for use.
It can be applied with fully automated Coagulation analyser systems to operate the pump system.

The Solution in unopened tanks should not be applied to Coagulation Analysers beyond the expiry date indicated on the label. Avoid freezing, optimal storage temperature is (18 to 25°C). Opened tanks should be consumed within max. 3 years.

## Units / consumption

| Cat.No. | 21 500 01 | 21 500 00 | 21 500 09 |
|---|---|---|---|
| Content | 1 x 1,25 L | 3 x 1,25 L | 9 x 1,25 L |

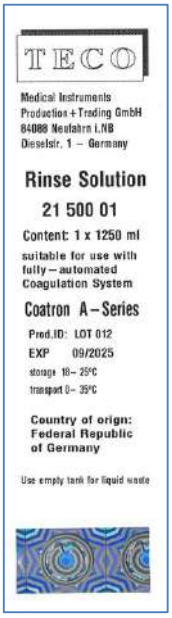
## Precautions and Waste information
The Solution should be used once only.
Ingredients: Laboratory water pH 7.0 (± 1,0 at 37 °C ± 1 °C)
Collected used solution should be disposed as prescribed in local regulations. No further precautions.

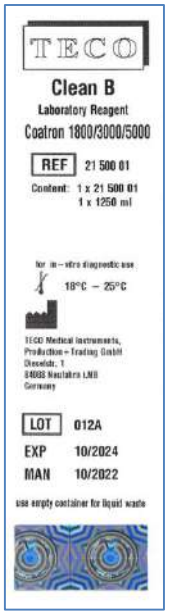
## Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

## Packaging Material, Dim.
Carton (3): (mm) L310 x W250 x H140
Carton (9): (mm) L310 x W250 x H330
PP (Tank): (mm) L110 x W300 x H80
Tank with Screwcap (PP) with inner PE Foil.
Tank additionally sealed with aluminium Foil.

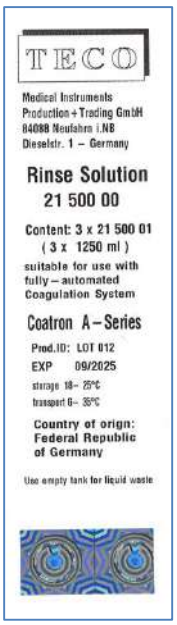
## Product picture (exemplary)


Placement of Label




Label Artwork ( with Hologram )






outer Packaging:

# 21 500 01 / 21 500 00 / 21 500 09
# Rinse Solution / Clean B

## Gebrauchsinformation
Die Lösung als allgemeiner Laborartikel für ein breites Spektrum von Anwendungen in Laboratorien eignet sich auch für den Einsatz bei in-vitro-diagnostischen Tests.

Die Lösung ist gebrauchsfertig. Sie kann mit voll-automatischen Gerinnungsanalysesystemen zum Betrieb des Pumpensystems verwendet werden.

Spüllösung in ungeöffneten Behältern sollte nach Ablauf des auf dem Etikett angegebenen Verfalls-datums nicht mehr in Gerinnungsanalysegeräten verwendet werden. Die Lagertemperatur sollte
(~18-25°C) betragen. Geöffnete Tanks sollten innerhalb von max. 3 Jahren verwendet werden.

## Verkaufseinheiten

| Kat.No. | 21 500 01 | 21 500 00 | 21 500 09 |
|---|---|---|---|
| Inhalt | 1 x 1,25 L | 3 x 1,25 L | 9 x 1,25 L |

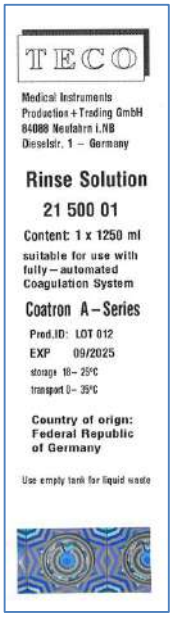
## Vorsichtsmassnahmen und Entsorgungshinweise
Die Lösung sollte nur einmal verwendet werden.
Bestandteile: Laborwasser pH 7,0 (± 1,0 bei 37 °C ± 1 °C)
Aufgefangene gebrauchte Lösung sollte gemäß den örtlichen Vorschriften entsorgt werden. Keine weiteren Vorsichtsmaßnahmen.

## Gewährleistung
Für dieses Produkt wird garantiert, dass es in Übereinstimmung mit den Angaben auf dem Etikett und in der Literatur funktioniert. TECO lehnt jede stillschweigende Garantie für die Marktgängigkeit oder die Eignung für einen anderen Zweck ab, und TECO haftet in keinem Fall für Folgeschäden, die sich aus der oben genannten ausdrücklichen Garantie ergeben.

## Verpackung
Karton (3): (mm) L310 x W250 x H140
Karton (9): (mm) L310 x W250 x H330
Tank (PP): (mm) L110 x W300 x H80
Tank mit Schraubdeckel PP Schaumfolie innen PE.
Tank zusätzlich versiegelt mit Aluminiumfolie

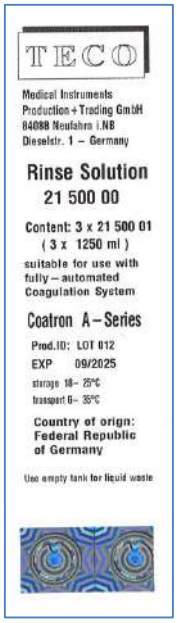
## Produktbilder (exemplarisch)

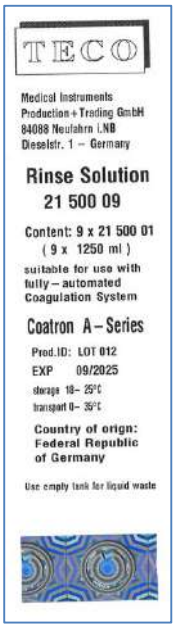
Platzierung

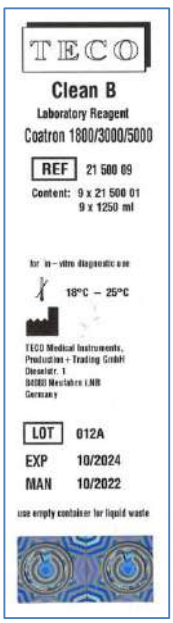




Label Layout ( mit Hologramm )




Umverpackung

# 21 510 00
# Clean Solution / Clean A

## Information of Use
The Clean Solution (Clean A) is intended as a general laboratory article for a wide range of uses in laboratories. It is also suitable for use in automatically coagulation analysers which are used for in vitro diagnostics tests.

TECO recommend it to remove any residues from needle probe on following TECO instruments: **Coatron A4, Coatron A6, Coatron A6 Plus: Coatron 1800 / 3000 / 5000.**

## Contents & Composition

| | |
|---|---|
| Product | Clean Solution (Clean A) |
| Cat.No. | 21 510 00 |
| Content | 1 x 500 ml |

Ingredients: 99,6% acidic solution (pH 1.1±0.5) with detergent (slight foaming); generally no hazardous to water.

## Preparation and waste information
Ready to use. The solution should be used once only.

## Storage and
Avoid freezing, best storage temperature (~18 – 25°C)

## Stability
See individual Expiry date on each box.

## Precautions
General laboratory safety measures for use of chemical solutions. Avoid direct contact with eyes and skin.

## 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.

## Product picture (example)


Clean Solution
( both with Hologram)


Clean A

## Outer Package
no specific outer package of single unit
Shipping within total packaging

Safety data sheet: sds-id.com/100202-6

Symbols key (if applicable):

| | | | | | |
|---|---|---|---|---|---|
| Temperature | Manufacturer | LOT | LOT Number | REF | Catalogue Number |

# 24 100 00 Single Cuvettes - 500
# 24 200 00 Single Cuvettes - 5000

## Information of use

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

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

## Content

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

The Cuvettes can be used with Coatron X Analyzers.

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

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

## Precautions and waste information

The Cuvette should only be used once in analyzers. To prevent contamination (sample/reagent), it is advised to avoid contact with skin and eyes. Suitable protective clothing and gloves are recommended.
Please also note the disposal of components in accordance with local regulations for infectious material.

Material: pure, clear Polystyrol (PS)

Maximum volume should be less than ~ 500µL

Minimum volume: 75 µL

Dimensions max.: Ø11,5 mm x 24 mm

## 24 100 00

Example Picture of the package – 500 Single Cuvettes


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

**Voucher** Single Cuvettes
**VIN:** 71101 XXXXX Σ
**PIN:** 19823 78881 500

Example of Voucher – 500 Single Cuvettes/Pack

## 24 200 00

Example Picture of the package – 5000 Single Cuvettes


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

**Voucher** Single Cuvettes
**VIN:** 71200 XXXXX Σ
**PIN:** 19823 78881 5000

Example of Voucher – 5000 Single Cuvettes/Pack

# 24 100 00 Single Cuvettes - 500
# 24 200 00 Single Cuvettes - 5000

## Gebrauchsinformation

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

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

## Inhalt

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

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

Dazu enthält jede Packung ein Voucher-Etikett mit einem VIN- und PIN-Code, um ein Ticket auf der webbasierten Registrierungsseite zu generieren (www.teco-reg.com).
Die Ticketinformationen (VIN/PIN) müssen für das jeweilige Gerät eingegeben werden, um die Anzahl der Tests für dieses Gerät freizugeben. Die (VIN/PIN) kann nur einmal pro Einheit verwendet werden.

## Vorsichtsmaßnahmen und Entsorgungshinweise

Die Küvette sollte nur einmal im Analysegerät verwendet werden. Um eine Kontamination (Probe/Reagenz) zu vermeiden, ist es ratsam, den Kontakt mit Haut und Augen zu vermeiden. Es werden geeignete Schutzkleidung und Handschuhe empfohlen.
Bitte beachten Sie auch die Entsorgung der Komponenten in Übereinstimmung mit den örtlichen Vorschriften für infektiöses Material.

Material: klares Polystyrol (PS)

maximales Volumen: nicht über ~ 500µL

ninimales Volumen: : 75 µL

max. Abmessungen: Ø11,5 mm x 24 mm

## 24 100 00

Beispielbild – Packung mit 500 Einzelküvetten


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

**Voucher** Single Cuvettes
**VIN:** 71101 XXXXX
**PIN:** 19823 78881
Σ 500

Beispiel des Voucher – 500 Einzelküvetten/Pack

## 24 200 00

Beispielbild – Packung mit 5000 Einzelküvetten


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

**Voucher** Single Cuvettes
**VIN:** 71200 XXXXX
**PIN:** 19823 78881
Σ 5000

Beispiel des Voucher – 5000 Einzelküvetten/Pack

# 80 521 10 Cuvette block, (4pos/ea)

## Information of use

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

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

## Content

| | | |
|---|---|---|
| Product | Cuvette block | 1000 pcs |
| Cat.No. | 80 521 10 | |
| Content | 50 bundles (= 20 blocks 4 pcs.) | 4000 det. |

The Cuvettes can be used with Coatron A (1800) Analyzers.

Depending on configuration of IVD analyser instrument a cuvette "activation"-code could be necessary. In this case the box contains an appropriate Voucher with a VIN and PIN code to generate a ticket on the web-based registration page (www.teco-reg.com).

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

## Precautions and waste information

The Cuvette should only be used once in analyzers. To prevent contamination (sample/reagent), it is advised to avoid contact with skin and eyes. Suitable protective clothing and gloves are recommended.
Please also note the disposal of components in accordance with local regulations for infectious material.

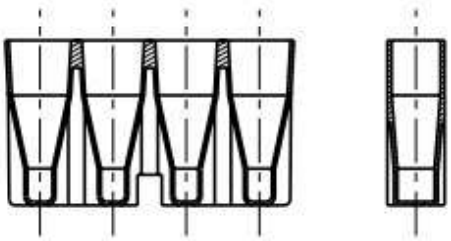
Material: pure, clear Polystyrol (PS)

Maximum volume per Single use Unit should be

less than ~ 1000µL

Minimum volume: 150 µL

Dimensions max.: (mm) L48 x H27 x W9,5



## 80 521 10

Example Picture of the package – 1000 Cuvettes blocks

Packaging:

1. Card Box, Dim.: (mm) 410 x 260 x 145
2. Labeling (see below)


Symbols key (if applicable):

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Manufacturer | LOT Lot. Number | REF Catalogue Number | Consult accompanying documents | Determination | Single use |

# 80 521 10 Cuvette block, (4pos/ea)

## Gebrauchsinformation

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

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

## Inhalt

| | | |
|---|---|---|
| Product | Küvetten Block | 1000 Stck. |
| Kat.Nr. | 80 521 10 | |
| Inhalt | 50 Bündel (=20 Blöcke/ 4Stck.) | 4000 Best. |

Die Küvetten können mit dem voll-automatischen Koagulations System Coatron A4 (1800) verwendet werden.

Je nach Konfiguration des IVD-Analysegerätes kann ein Küvetten-"Aktivierungs"-Code erforderlich sein. In diesem Fall enthält die Box einen entsprechenden Voucher mit einem VIN- und PIN-Code, um ein Ticket auf der webbasierten Registrierungsseite (www.teco-reg.com) zu generieren.

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

## Vorsichtsmaßnahmen und Entsorgungshinweise

Die Küvette sollte nur einmal im Analysegerät verwendet werden. Um eine Kontamination (Probe/Reagenz) zu vermeiden, ist es ratsam, den Kontakt mit Haut und Augen zu vermeiden. Es werden geeignete Schutzkleidung und Handschuhe empfohlen.
Bitte beachten Sie auch die Entsorgung der Komponenten in Übereinstimmung mit den örtlichen Vorschriften für infektiöses Material.

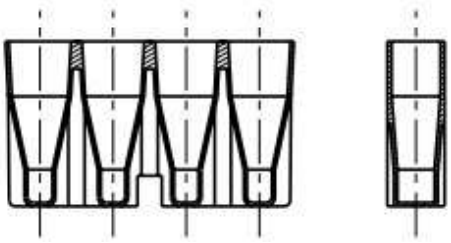
Material: pure, clear Polystyrol (PS)

Maximum volume per Single use Unit should be

less than ~ 1000µL

Minimum volume: 150 µL

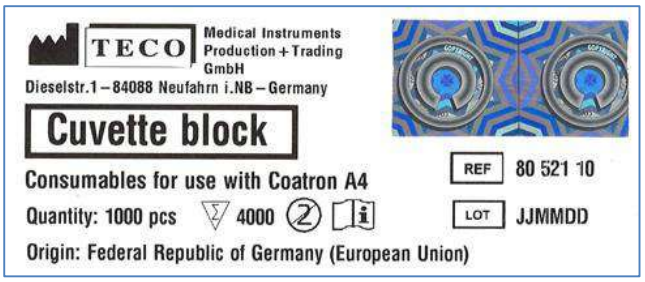
Dimensions max.: (mm) L48 x H27 x W9,5



## 80 521 10

Beispielbild – Packung mit 1000 Küvetten Blöcken

Verpackung:
1. Karton, Maße: (mm) 410 x 260 x 145
2. Etikett – siehe unten




Symbole (wenn zutreffend):

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Hersteller | LOT Chargen Nr. | REF Katalog Nummer | Begletidokumente beachten | Anzahl Bestimmungen | Einmalgebrauch |