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, 2023 to December 31st, 2024

Termination: Confirmation ends automatically on Dec. 31st of 2024 and must be then renewed.

Products:

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

all instruments with complete accessory, consumables and spare parts

- Hemostasis Reagents — Complete product line

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

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl

Medical Instruments TECO Production+Trading GmbH

Digitally signed by Dolgopol Iulian
Date: 2024.02.08 09:58:31 EET
Reason: MoldSign Signature
Location: Moldova

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

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

TECO

CE

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

Doc#200/08-2022

Hersteller / Manufacturer:	**TECO Medical Instruments Production + Trading GmbH**
Adresse / Address:	**Dieselstrasse 1, 84088 Neufahrn, Germany**
Marktakteur / Actor ID SRN:	**DE-MF-000022642** https://ec.europa.eu

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

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

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

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

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

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

Sie entsprechen den anwendbaren Anforderungen der Richtlinie:	They meet applicable requirements of:
Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert gemäß Artikel 9 als "alle anderen Produkte"	Directive 98/79/EC on in-vitro-diagnostic medical devices classified according to article 9 as „all other products"
Die Qualitätssicherung entspricht den Anforderungen der Richtlinie 98/79/EG über In-vitro-Diagnostika für diese Art von Produkten.	The Quality Assurance is in accordance with the requirements of Directive 98/79/EC on in-vitro-diagnostic medical devices for those kind of products.
Der implementierte QM-Prozess entspricht der EN ISO 13485:2021	The implemented QM Process complies with EN ISO 13485:2021
Die vorstehende Konformitätserklärung ist gültig für alle Chargen dieser Produkte, die nach dem Datum der Unterzeichnung in Verkehr gebracht wurden.	The above mentioned declaration of conformity is valid for all lots of this product, which are distributed after the date of signature.
Das Konformitätsbewertungsverfahren entspricht Anhang III der Richtlinie 98/79/EG über In-vitro-Diagnostika für diese Art von Produkten.	The conformity assessment procedure complies with Annex III of Directive 98/79/EC on in-vitro-diagnostic medical devices for those kind of products.

Ort und Datum der Unterzeichnung: Neufahrn, 2022-08-31
Place and date of issue:

Christian Hötzl
Verantwortliche Person / PRRC

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Doc#200/08-2022

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Directive 98/79/EC Annex A
Übrige Produkte – Reagenzien für In-vitro-Diagnostika
Other products – Reagents for in vitro diagnostic – general IVD

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

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

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

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

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

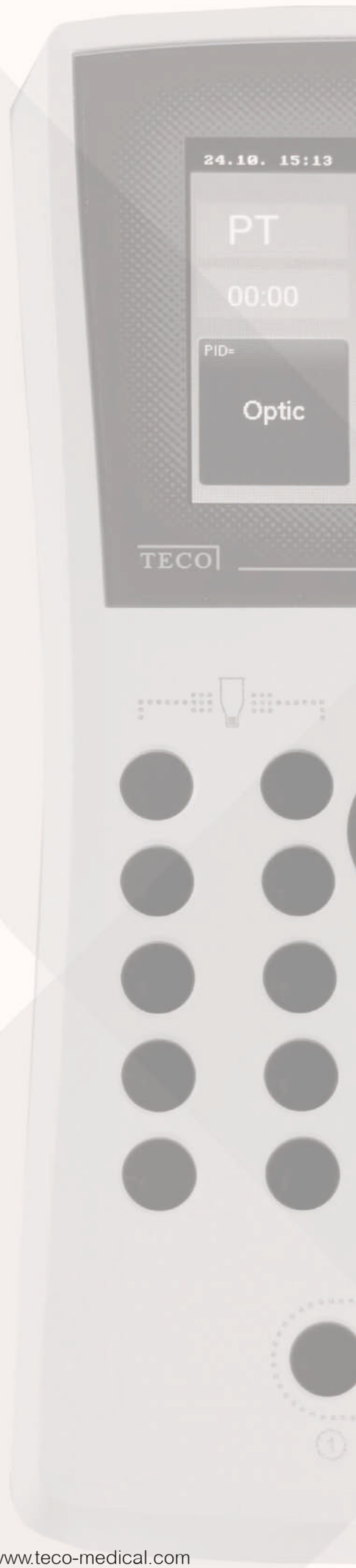
The remarkable details in every single component is achieved by selecting of premium suppliers.

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

Manual de operare

Seria X Coatron

Eco / Pro / Top

IVD

CE

REP

Doar pentru diagnosticul in-vitro

Dispozitive și reagenți pentru coagulare și hemostază

OPM Revizuirea 1
Program V01.00.39
Document No: 26 900 01

Reprezentant autorizat în Republica Moldova:
SANMEDICO SRL
mun. Chișinău, str. Petricani 88/1, of.10
tel: (022) 623 032; 060 155 788

Actualizări

VERSIUNEA INSTRUCȚIUNII UTILIZATORULUI	VERSIUNEA PROGRAMULUI
1	1.00.39 (prima ediție)

Drepturi de autor

Mărcile comerciale

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

Producătorul

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

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

Garanție

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

Garanția expiră în caz de defecțiuni cauzate de:

- Accident, neglijență în întreținere și înșelăciune, abuz sau utilizarea necorespunzătoare.
- Folosirea de reactivi, materiale consumabile sau piese de schimb neautorizate.
- Deservirea neautorizată. Orice reparație sau deservire trebuie efectuată de persoane autorizate.

Lista imaginilor din manual:

1. INTRODUCERE

Acest dispozitiv a fost fabricat în condiții de maximă eficiență în ceea ce privește siguranța și funcționalitatea sa de inginerie. Pentru a menține această condiție și a asigura o operare fără riscuri, operatorul trebuie să respecte avertismentele și informațiile de siguranță din acest manual de utilizare.

Folosiți Coatron X numai în conformitate cu instrucțiunile din acest manual de utilizare. În caz contrar, producătorul exclude răspunderea pentru daunele aduse dispozitivului Coatron X, pacienților sau operatorilor.

1.1 SIMBOLURI

Următoarele simboluri standard sunt utilizate în acest manual:

SIMBOL	Semnificația	Explicația
Courier	**Informație**	Buton pe tastatură
CAPS	**Informație**	Mesaj pe ecran
	**Citire**	Indică informație importantă și sfaturi
⇨	**Informație**	Descrie reacția Coatron X la intrarea făcută de operator.
	**Atenție**	Risc de posibile daune de sănătate sau daune considerabile echipamentului dacă nu se ține cont de avertisment.
	**Pericol**	Risc potențial pentru personalul care operează cu echipament sau pentru dispozitiv din cauza șocului electric.
	**Pericol biologic**	Echipamentul poate fi potențial infecțios datorită probelor și reactivilor folosiți.
	**Radiație laser**	Evitați expunerea directă a ochilor

1.2 IMAGINI CU DISPOZITIVUL

Ecranul principal

Ecran tactil color

Zona completată este preîncălzită până la 37°C

1 x poziția reagentului Ø24mm

1 x poziția reagentului Ø22mm

1 x poziția reagentului Ø22mm, amestecat

2 x pozițiile reagentului Ø13mm

20 x pozițiile de incubare ale cuvetelor

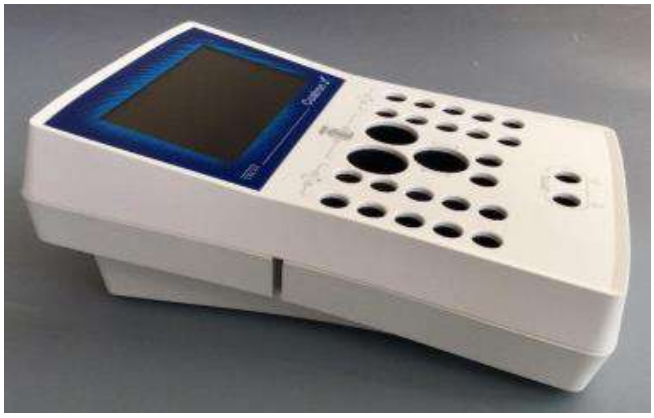
4 x pozițiile de măsurare a cuvetelor

(depinde de versiunea ECO/PRO/TOP)

Imaginea 1: Vedere de sus

5V: Cablul de energie
PC: LIS sau PC
DESERVIRE: Actualizarea programului
IMPRIMANTĂ: Impriantă în serie
CODUL DE BARE: Scaner de mînă a codurilor de bare

Imaginea 2: Vedere din spate



5V: Cablul de energie
PC: LIS sau PC
DESERVIRE: Actualizarea programului
IMPRIMANTĂ: Impriantă în serie
CODUL DE BARE: Scaner de mînă a codurilor de bare

Imaginea 3 : Vederea laterală cu slotul pentru codul de bare

1.3 UTILIZAREA PROPUSĂ

IVD

Familia COATRON-X este proiectată pentru a efectua teste coagulometrice, cum ar fi PT, PTT, TT, fibrinogen, teste cu un singur factor, teste cromogene și imunoturbidimetrice (de exemplu, antitrombină, D-dimer etc.) pe plasmă citrată umană. Aparatul trebuie utilizat în scopurile preconizate și în condiții tehnice perfecte, de către personal calificat, în condiții de muncă și operațiuni de întreținere, așa cum este descris în acest document. Este conceput pentru mediu de laborator sau clinic și pentru a fi operat de un utilizator instruit. Nu este destinat uzului casnic.

1.3.1 COMPARAȚIA DISPOZITIVELOR COATRON X

Coatron-X este disponibil în trei versiuni diferite numite Eco, Pro sau Top.

Coatron-X	**Eco** 	**Pro** 	**Top** 
Canalele optice	1	2	4
Lungimea de undă optică	620nm	405nm	405nm
Cuvete, volum total	Singular, 75µL	Singular, 75µL	Singular, 75µL
Analize totale de coagulare	PT+aPTT+Fib+TT		
Analize speciale de coagulare	-	Toți factorii	Toți factorii
Analize cromogene	-	AT, PC	AT, PC
Analize avansate latex	D-Dimer		
Testarea sângelui integru	Da (PT INR+%)	Nu	Nu
Ecran	TFT 4.3'' , 480x272 , 18bit color, multi-touch		
Parametrii fizici	Forma X 225x150x90mm (LxlxÎ) cu imprimeu tampon		
Blocarea reagenților și optică	Preîncălzit la 37°C		
Preîncălzirea cuvetelor	10x	20x	20x
Preîncălzirea reagenților, 24mm	1x		
Preîncălzirea reagenților, 22mm	2x		
Preîncălzirea reagenților, microtuburi	2x		
Agitator de reagenți	nu	1x	1x
Interfața pentru imprimanta din serie	Da		
Interfață pentru scanerul de coduri de bare portabil	Da		
Modulul scanerului de coduri integrat	opțional		
LIS, USB	Da		

Actualizarea programului, USB	Da
Bluetooth V4.0	Urmează

Funcțiile utilizatorului	Eco	Pro	Top
Utilizare intuitivă prin Touchscreen nu este necesară experiență sau pregătire	Da		
Algoritmul de coagulare TECO avansat Cel mai bun din experiența de 25 de ani	Da		
Lotul de reagent dublu gestionați două loturi diferite pentru fiecare test	Nu	Da	Da
Barcodul de reagenți LOT de intrare + Detectare LOT de expirare sau LOT pozitiv	Da		
Calibrarea testului LOT, expirare și maximum 5 puncte pentru fiecare test	Da		
Codul de bare a pacientului Introduceți ID-ul pacientului prin scanerul de coduri de bare până la 16 caractere	Da		
Baza de date a rezultatelor Salvați rezultatele în dispozitiv	Nu	Da	Da
Determinarea dublă Rulați pacientul de două ori și afișați valoarea medie	Nu	Da	Da
Funcția cronometru Cronometrați timpul de incubare	1x	2x	4x
Identificarea rezultatelor Numărul de identificare al pacientului, a mostrei sau autoidentificare	Da		
Ceas în timp real Funcția dată și timp	Da		
Modificarea limbii EN,ESP, ITA, FR,DE – în continuare ca opțiune	Da		
Începeți testarea la adăugarea reagentului Nu este necesară o pipetă de start scumpă	Da		
Vizualizați curba de reacție Este necesar programul Tecmoni	Da		
Link către LIS prin USB Protocolul programului TECAM SMART	Da		
Link către LIS prin rețea / ASTM Este necesar programul TECAM SMART	Da		

1.3.2 METODE DE TESTARE

Următoarele teste sunt furnizate pentru a detecta afecțiunile sistemului de coagulare uman, care pot fi sângerare sau tromboză și monitorizarea medicamentelor anti-coagulare precum Heparin sau Marcumar.

Testul	Denumirea	Specimen	Coatron X		
			Eco	Pro	Top
PTB	Timpul de protrombină	Sînge	Da	Nu	Nu
PT	Timpul de protrombină	Plasmă	Da	Da	Da
aPTT	Timpul protrombinic parțial activat	Plasmă	Da	Da	Da
FIB	Fibrinogenul	Plasmă	Da	Da	Da
TT	Timpul trombinei	Plasmă	Da	Da	Da
AT	Antitrombina	Plasmă	Nu	Da	Da
DD	D-Dimer	Plasmă	Da	Da	Da
PC	Proteina C	Plasmă	Nu	Da	Da
Factors	Factorii II, V, VII, VIII, IX, X, XI, XII	Plasmă	Nu	Da	Da

1.3.3 COLECTAREA MOSTRELOR

Tipul:	Plasmă citrată umană
Colectarea:	puncția venei, 1:10 citrat de sodiu mixt 3.2% (0.105M)
Centrifugarea:	10 min la 1500g
Păstrarea:	Max 4h după colectare, la temperatura camerei
Bilirubina:	< 50mg/dl
Hemoglobina:	< 2000mg/l
Trigliceridele:	< 50g/l

<u>Specimen destinat pentru PTB (Coatron X Eco)</u>

Tipul:	sânge capilar din puncția degetului, sînge integru citrat

În cazul în care există diferențe față de elementele de siguranță ale reactivului, urmați întotdeauna instrucțiunea din cutie.

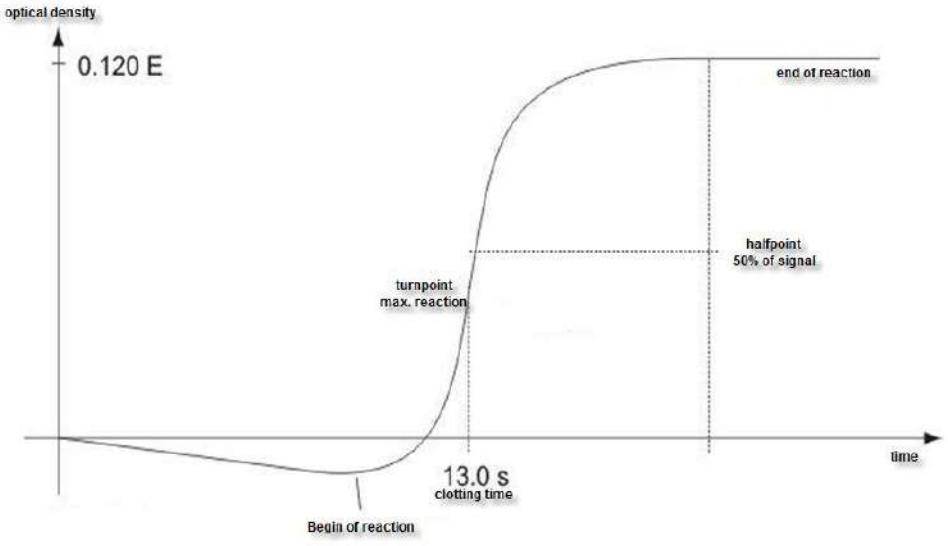
1.3.4 PRINCIPIUL DE MĂSURARE

Detectarea coagulării plasmatice se bazează pe principiul fotometric. Nu sunt necesare accesorii mecanice precum bilele de amestecare. Plasma de sânge este turnată într-o cuvă. Se adaugă reactivi speciali, care inițiază coagularea sângelui. Cuva este expusă prin lumină ultravioletă în timpul procesului de coagulare. Când proba începe să coaguleze, se măsoară o schimbare a absorbției luminii. Timpul de la începerea măsurării până la schimbarea luminii (punct de cotitură) se numește timp de coagulare și se exprimă în secunde [s].
Conversia timpului de coagulare într-o unitate de test specifică este una folosind o interpolare liniară, hiperbolică, semi-logaritmică sau dublu-logaritmică a punctelor de calibrare stocate. Modelul matematic actual este tipărit în „SETUP TEST”. Valorile în afara domeniului de calibrare sunt calculate prin extrapolare și marcate ca " * ".

Unitate	Informație	Locurile decimale	Valoare maximă
s	secunde	1	-
%	activitate	1	180.0
U	unități	0	999
INR	Raport int.	2	30.00
R	raport	2	30.00
NR	raport polonez	0	180
mg/dl		0	900
g/l		2	10.00
IE/ml	Unități int.	2	10.00
mg/l		2	10.00
µg/ml		3	7.000
ng/ml		0	7500
µg/l		0	7500
IU/mL	Unități int.	2	10.00

R = timpul de coagulare / timpul normal
NR = 100 *(timpul normal / timpul de coagulare)
INR = Ratio ^{ISI} (Raport normal internațional)
IU/mL = IE/mL = Unități internaționale (1.00 IU/mL = 100 % activitate)

1.3.5 METODA DE COAGULARE (PT, APTT,..)



IMAGINEA 4: DETERMINAREA PUNCTULUI DE ÎNTOARCERE ÎN METODA DE COAGULARE

Reacția finală în cascada de coagulare este transformarea fibrinogenului în fibrină catalizată de trombină. Formarea fibrinei are ca rezultat oglindirea (nivel turbidimetric mai mare) în probă, care este măsurată de fotometru și stocată ca dispariție. Rezultatul în câteva secunde este timpul de la începutul reacției până la momentul vitezei maxime de schimbare (punctul de cotitură al reacției). Dispozitivul poate fi comutat și pentru a defini coagularea la jumătatea punctului de reacție.

1.3.6 METODA CROMOGENĂ (ANTITROMBINA):

Schimbarea semnalului optic nu este cauzată de reacția de cheag, ci de eliberarea de particule de culoare (pNA), care provoacă o culoare galbenă. Schimbarea culorii este măsurată la 405 nm și exprimată ca „dE/60sec" și proporțională cu concentrația sau activitatea analitului.

1.3.7 METODA IMUNOTURBIDIMETRICĂ (D-DIMER):

Schimbarea luminii este cauzată de reacțiile Antigen - anticorp, care au dispersat lumina. Anticorpii se leagă de particulele de latex la amplitudinea reacției optice. Schimbarea luminii este proporțională cu concentrația de antigen precum D-Dimer și exprimată ca dE/120 sec.

1.4 INFORMAȚIA CU PRIVIRE LA SIGURANȚĂ

1.4.1 INFORMAȚII DE SIGURANȚĂ PENTRU FUNCȚIONARE

Folosiți numai lichidele de curățare și clătire aprobate de producător. Nerespectarea acestui lucru poate duce la măsurări defectuoase sau defecțiuni ale reactivilor Coatron X. Preveniți scurgerile în analizator. În caz contrar, este necesar ca lucrările de întreținere costisitoare să fie necesare!

Efectuați măsurări de control la intervale regulate pentru a vă asigura că analizorul continuă să funcționeze impecabil .

Dacă dispozitivul este utilizat într-o manieră, care nu este specificată de producător, garanția ar putea fi afectată!

Vă rugăm să citiți manualul de utilizare în întregime înainte de operare. Pentru a asigura un nivel ridicat de performanță și pentru a evita erorile utilizatorului.

1.4.2 INFORMAȚII DE SIGURANȚĂ PENTRU MATERIALE

Folosiți numai materiale aprobate și etichetate TECO, cum ar fi cuvete, piese de schimb sau reactivi pentru care dispozitivul este destinat și validat.

Consumabile precum cuvete sau vârfuri galbene sunt destinate obiectelor de unică folosință. Utilizarea repetată poate duce la rezultate false din cauza contaminării. Urmați instrucțiunile din circularele pachetului de reactivi. Utilizarea incorectă poate duce la rezultate false.

Nu folosiți materialele după data de expirare. Reactivii IVD în special expirați pot provoca rezultate false.

Controlați funcția corectă a pipetei manuale în fiecare an pentru a asigura rezultate precise.

1.4.3 INFORMAȚII DE SIGURANȚĂ PRIVIND RISCUL PENTRU SĂNĂTATE

Sângerare sau tromboză

Diagnosticul și medicația sistemului de coagulare uman bazat pe rezultate false poate duce la sângerare critică sau tromboză. Pentru reducerea riscurilor, este esențial să urmăriți indicațiile de mai jos.

Provocată din cauza stării de eroare a dispozitivului, a reactivului sau a datelor de calibrare:

Efectuați un control al calității înainte de a rula o serie de probe de pacient sau după reconstituirea unui flacon sau după calibrarea testului pentru a exclude erorile de date ale dispozitivului, reactivului sau calibrării.

Provocată de o pipetă imprecisă:

Validați pipeta în fiecare an și etichetați ultima dată de validare.

Provocat de alocarea falsă a valorilor țintă

Executați standardele interoperaționale de control al calității.

Provocat de apa purificată

Folosiți doar apă purificată pentru a reconstitui controale sau reactivi. Verificați vizual ca apa să nu conțină impurități.

Provocat de reactivul expirat

Nu folosiți reagentul *in vitro* sau materialele după data lor de expirare.

Material contaminant

Aveți în vedere toate suprafețele și materialele, care ar putea intra în contact cu plasmă sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.

Evitați contactul

Purtați mănuși de protecție contra infecțiilor medicale pentru toate lucrările, care implică un contact potențial cu materiale infecțioase și utilizați fiecare pereche de mănuși o singură dată. Folosiți un produs dezinfectant pentru mâini, de ex. Sterilium®, pentru a dezinfecta mâinile după finalizarea lucrărilor.

Aruncați

Materialele infecțioase, cum ar fi deșeurile de cuvă și deșeurile lichide, în conformitate cu legile locale, care reglementează materialele infecțioase.

Condițiile de igienă

Validează sistemul de management igienic în conformitate cu biroul federal german GLP pentru bune practici de laborator sau standarde de calitate similare. Orice deșeuri trebuie considerate potențial infecțioase. Trebuie evitat contactul direct. Sunt necesare mănuși de protecție în timpul funcționării, deservirii sau curățării.

Radiație cu lumină LED
Evitați expunerea directă a ochilor.
Scanerul intern de coduri de bare CCD este atribuit
EN 55022:2010 clasa B, EN 62471:2008

1.4.4 INFORMAȚII DE SIGURANȚĂ PENTRU CURĂȚARE, ÎNTREȚINERE ȘI DESERVIRE

Despre deservirea autorizată!
Efectuați numai măsurile de întreținere, reparație și înlocuire enumerate în acest manual de utilizare. O manipulare necorespunzătoare a dispozitivului va anula obligațiile de răspundere ale producătorului și poate face necesară efectuarea apelurilor de servicii, a căror plată nu este acoperită de garanție. Numai Serviciul Clienți autorizat poate efectua reparațiile. Se pot folosi numai piese de schimb originale. Înainte de a efectua orice reparație pe dispozitiv, este foarte important să dezinfectați complet toate piesele posibil contaminate.

Despre curățire și decontaminare!
Înainte ca dispozitivul să fie scos din laborator pentru eliminare sau întreținere, acesta trebuie decontaminat. Procedura este descrisă în capitolul „Curățare și întreținere” și trebuie efectuată doar de personal autorizat bine instruit, respectând toate măsurile de siguranță necesare.

Certificatul de decontaminare este necesar!
Dispozitivele, care trebuie returnate trebuie să fie însoțite de un certificat de decontaminare completat de responsabilul de laborator. Dacă nu este furnizat un certificat de decontaminare, laboratorul de returnare va fi responsabil pentru taxele rezultate din neacceptarea dispozitivului de către centrul de deservire.

Aveți în vedere toate suprafețele și materialele care ar putea fi în contact cu plasmă sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.

Evitați orice contact direct cu decontaminanți sau dezinfectanți.

1.4.5 SIGURANȚA ELECTRICĂ

	**Precauții:** ▪ Evitați lichidele vărsate în sistem. Dar în cazul în care acest lucru se întâmplă, deconectați dispozitivul de la sursa de energie și curățați și uscați toate părțile contaminate. ▪ Scoateți cablul de alimentare înainte de a deschide dispozitivul. ▪ Nu atingeți piesele electronice în timpul funcționării. ▪ Nu folosiți sistemul fără o conexiune adecvată la împământare. ▪ Nu întrerupeți niciodată intenționat contactele de protecție la sol. ▪ Nu îndepărtați niciodată elementele carcasei, capacele de protecție sau elementele structurale securizate, deoarece acest lucru ar putea expune piese, care transportă curent electric. ▪ Asigurați-vă că suprafețele precum podeaua și masa de lucru nu sunt umede în timp ce se lucrează pe dispozitiv. ▪ Verificați regulamentul echipamentelor electrice. Conductele sau soclurile defecte trebuie înlocuite fără întârziere.

	**Conectați la energie:** ▪ Dispozitivul este clasificat în clasa 1 (IEC) și, prin urmare, trebuie să fie legat în mod fiabil și instalat profesional, în conformitate cu reglementările în vigoare privind cablurile electrice și cu standardele de siguranță prevăzute aici. ▪ Asigurați-vă că setarea tensiunii de funcționare este corectă înainte de a conecta dispozitivul la rețeaua de alimentare. Citiți capitolul „Instalare” despre condițiile electrice.

	**Deconectați de la energie:** ▪ Deconectați cablul de alimentare de la priza de perete sau de la sursa de alimentare a dispozitivului.

1.4.6 DECLARAȚIA EMC

Coatron X respectă cerințele privind emisiile și protecția, în conformitate cu GB/T 18268.1 (IEC 61326-1: 2012) și GB/T 18268.26 (IEC61326-2-6: 2012).

Coatron X a fost proiectat, testat și găsit în conformitate cu dispozitivul Clasa A, în conformitate cu GB 4824 (IEC 61000-4). În mediul intern, acest dispozitiv poate provoca interferențe radio, caz în care utilizatorul este obligat să ia măsuri adecvate.

Detectarea mediului electromagnetic este recomandată înainte de a utiliza acest dispozitiv.

Evitați să acționați acest dispozitiv în apropierea unei surse de radiație puternică (de exemplu, o sursă RF ne-ecranată), care poate interfera cu funcționarea corectă a dispozitivului.

Lungimea maximă a cablurilor către dispozitivele externe precum imprimanta, codul de bare sau LIS trebuie să fie mai mică de 3 m pentru a păstra conformitatea cu EMC. (IEC 61326-1:2012)

Nu instalați pe masa metalică de 3m.

1.4.7 RECICLAREA DISPOZITIVULUI

Sistemul trebuie decontaminat de deșeurile electrice înainte de transportare către un dispozitiv autorizat.

Dispozitivul trebuie reciclat, așa cum este indicat de DEEE (2002/96/EG).

2. INSTALAREA DISPOZITIVULUI **COATRON X**

2.1 OBIECTUL LIVRĂRII

Pachet de livrare standard

- 1 buc. **Coatron X**
- 1 buc. Sursa de energie
- 25 buc. Cuvete de unică folosință
- 5 buc. Tuburi pentru reagenți
- 1 buc Manualul utilizatorului

Imaginea 5: Setul standard la livrare

Opțional sunt disponibile:

- Imprimantă termică
- Cablul imprimantei
- Rulouri de hîrtie pentru imprimantă (5/ea)
- Pipetă cu volum variabil 10 -100 µl, simplă
- Programul TECAM Smart

2.2 CONDIȚII DE LUCRU

Condițiile de mediu:

Temperatura de operare	15 - 30 °C
Umiditatea	< 70%
Ridicarea deasupra nivelului mării	< 3.000m
Protecție de praf	Gradul 2
Rezistența la impact	În conformitate cu IEC/EN 61010-1, 8.2.2
Nu este permis	Vibrații, lumină directă a soarelui; expunerea directă la condițiile de aer.

Condițiile electrice:

100-240 VAC, 47 - 63Hz, Clasa-1 (61010)

Condițiile de păstrare:

0°C to +40°C, maxim 12 luni în ambalajul original

Condițiile de transportare:

0°C - +40°C, < 70% umiditate relativă

Nu este definit special. Regulamentul general pentru transport poate fi utilizat.

Condițiile de igienă:

Validat conform sistemului de management igienic în conformitate cu biroul federal german GLP pentru bune practici de laborator sau standarde de calitate similare. Orice deșeuri trebuie considerate potențial infecțioase. Trebuie evitat contactul direct. Sunt necesare mănuși de protecție în timpul funcționării, deservirii sau curățării.

2.3 DESPACHETAREA DISPOZITIVULUI **COATRON X**

Verificați ambalajul Coatron X și al accesoriilor pentru eventuale deteriorări vizibile. Dacă ambalajul este deteriorat, contactați compania de transport pentru a putea fi evaluată orice deteriorare a dispozitivului sau a accesoriilor.

Procedurile la prima instalare:

1. Despachetați și așezați dispozitivul în conformitate cu condițiile de funcționare (a se vedea cu un capitol înainte).
2. Conectați la sursa de energie.
3. Porniți și așteptați până la regimul verde.
4. Atingeți Green Status și selectați „print”.
5. Atașați raportul de sistem în „Înregistrare protocol de instalare” sau casetă.
6. Confirmați funcția corectă a sistemului printr-o măsurare de control al calității cu PT și plasmă de control.

<u>Instalarea programului TECAM Smart</u>

1. Deconectați dispozitivul de la calculator.
2. Rulați TECAM setup.exe.
3. Confirmați, atunci când vi se cere să instalați driver-ul Coatron X.
4. Conectați dispozitivul la calculator. PC-ul ar trebui să mesajeze, că a fost găsit un dispozitiv nou.
5. Reporniți TECAM.

Informații suplimentare pot fi citite în capitolul „7” sau ajutorul online TECAM.

Păstrați materialul de ambalare original pentru transportul ulterior.

2.4 PORNIREA ȘI OPRIREA

Pornirea
Conectați la sursa de energie.

Dispozitivul necesită aproximativ 15 min pentru încălzirea blocului optic la 37 ° C. După aceea este gata pentru măsurare, care este indicat cu un LED verde pe afișaj.

Oprire
Aparatul nu acceptă întrerupător de alimentare. Trebuie să se deconecteze de la energie.

Regim de așteptare
Comutarea sistemului în standby după 2 min de funcționare inactivă. În standby, luminozitatea afișajului este redusă pentru a economisi durata de viață a afișajului și pentru a reduce consumul de energie.

Regimul ”somn”
Deschideți meniul și atingeți butonul „Sleep”.

Meniul este afișat în partea de sus a ecranului și este disponibil numai dacă nu există nici măsurare. Consumul de energie în timpul somnului este de 0,2W.

”Trezirea”
Ecranul tactil.

Nu există niciun risc de deteriorare a sistemului sau de pierdere de date. Sistemul poate fi (de) conectat în orice situații de operare.

2.5 ÎNREGISTRAREA

Producătorul trebuie informat despre data primei instalări. Pentru aceasta, navigați pe site-ul web TECO GmbH www.teco-gmbh.com și conectați-vă cu datele contului dispozitivului, care sunt afișate în timpul pornirii sau a ecranului cu informații despre sistem sau pe placa de dispozitive.

User=	S/N	Numărul de serie, de exemplu 0104000005
Pass=	PIN	Numărul de identificare al produsului, de exemplu 1234 5678 90

2.6 GARANȚIA

Termenul de garanție va începe din data livrării sau înregistrării (prima instalare).

3. OPERAREA CU DISPOZITIVUL **COATRON X**

Coatron X este controlat în totalitate prin ecran tactil.

- Atingere scurtă: Funcția este executată la atingere
- Atingerea lungă: Funcția este repetată de 10 ori
- Textul butonului gri: Funcția este oprită
  În timpul măsurării active, unele funcții din meniu nu sunt vizibile sau afișate cu text gri. Opriți măsurarea pe toate canalele pentru a reactiva butoanele.

3.1 GHIDUL RAPID

Cum se execută o măsurare PT:

1. Porniți dispozitivul și așteptați starea verde (~ 15min până la 37 ° C).
2. Puneți flaconul PT în blocul de reactiv și lăsați să se incubeze timp de cel puțin 5 min.
3. Schimbați testul canalului 1 în „PT”.
4. Plasați cuva în optică.
5. Introduceți 25 ul de probă în cuvă.
6. Apăsați pe „00:00” și așteptați 30 sec.
7. Apăsați „OPTIC-1” și introduceți un PID sau scanați un cod de bare de probă.
8. Adăugați 50 uL reactiv PT, când „Activ” clipește. Măsurarea va fi începută.
9. Așteptați să se rupă rezultatul sau atingeți butonul optic.

Activarea multiplă (cu excepția Coatron ECO)

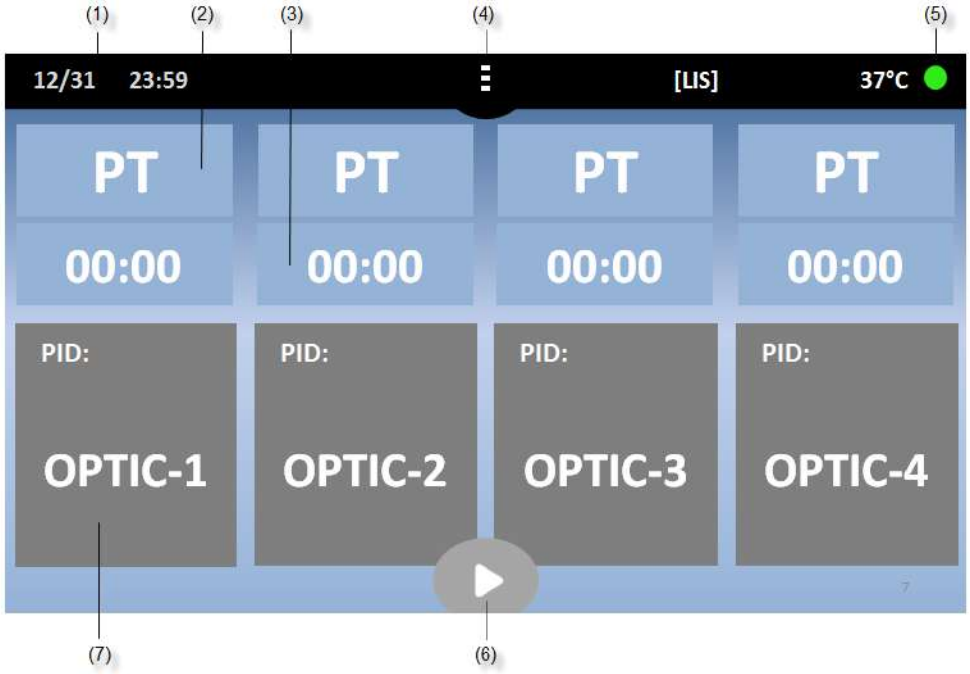
1. Deschideți meniul și setați Auto PID = Pornit.
2. Puneți cuve goale în fiecare canal și pipetați 25 ul de probă pe fiecare cuvă.
3. Apăsați butonul mutlistart.
4. Adăugați 50 ui PT la fiecare cuvă.

Cum se introduce o calibrare PT:

1. Porniți dispozitivul și treceți la ecranul de pornire.
2. Atingeți orice buton de testare.
3. Schimbați testul în „PT” și atingeți „Configurare” sau scanați codul de bare al flaconului PT.
4. Introduceți LOT, data de expirare și selectați Unități în „% + INR”.
5. Apăsați din nou butonul „Configurare”.
6. Selectați câmpul de date și schimbați cu butoanele incrementale (- / +). Utilizați funcția de atingere lungă pentru o introducere ușoară.
7. Confirmați cu „OK”.

3.2 MĂSURAREA

Primul ecran după pornire



IMAGINEA 6: ECRANUL DE BAZĂ COATRON X TOP

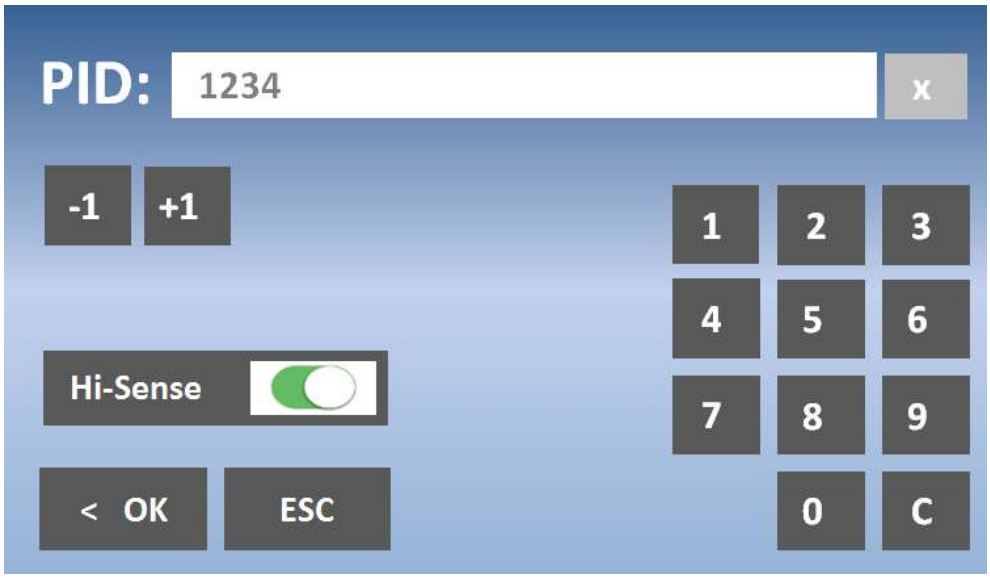
Butonul	Titlul	Utilizarea funcției
(1)	Data și timpul	Redactarea datei
(2)	Testarea curentă	Modificarea testului
(3)	Taimer	Start/Resetarea taimerului sau alarmei
(4)	Meniu sau Acasă	Deschideți meniul sau reveniți la principal
(5)	Verde sau Roșu	Deschideți informațiile despre sistem
(6)	Multistart	Activați toate canalele
(7)	Optic-1	Channel-1 este inactiv. Atingeți pentru a introduce un nou PID și activați
(7)	Activ	Canalul este activ. Atingeți sau adăugați reactiv pentru a începe
(7)	Portocaliu intermitent	Măsurarea continuă. Atingeți pentru a opri măsurarea
(7)	Rezultatul curent	Atingeți pentru a introduce un nou PID

Altele	
eșantion cod de bare	Citiți ID-ul pacientului și urmăriți activarea gratuită
[LIS]	Vizibil, dacă este conectat cu LIS
LED Verde	Sistemul este gata pentru măsurare
LED Roșu	Indică problemele sistemului. Nu este posibilă nicio măsurare.
37.0°C	Temperatura pe blocul de reactiv.
Butoane gri	Funcția de utilizare nu este posibilă în timpul măsurării.
Contrast întunecat	Modul de salvare. Atingeți pentru a reactiva.

IMAGINEA 7: ECRANUL ÎN TIMPUL MĂSURĂRII

Butonul (7) în timpul măsurării	
PID	Numărul de identificare al pacientului (maxim 16 cifre)
Rezultat	PT = 12.5s, 115% 0,91 INR +++ nici o reacție de cheag nu a fost detectată în timp de execuție
Indicator	f = fibrinogen foarte scăzut (cheag slab) F = fibrinogen foarte mare (cheag puternic) * = Rezultatul nu corespunde cu calibrarea X = valoarea dublă deviază mai mult decât 15%
Err	T = temperatura nu este la 36 - 38°C E = reagent expirat S = intensitatea luminii este prea joasă
mOD	absorbție optică curentă. O schimbare a valoare> 50mOD indică o reacție de cheag în curs.
Taimer	Ora curentă de măsurare

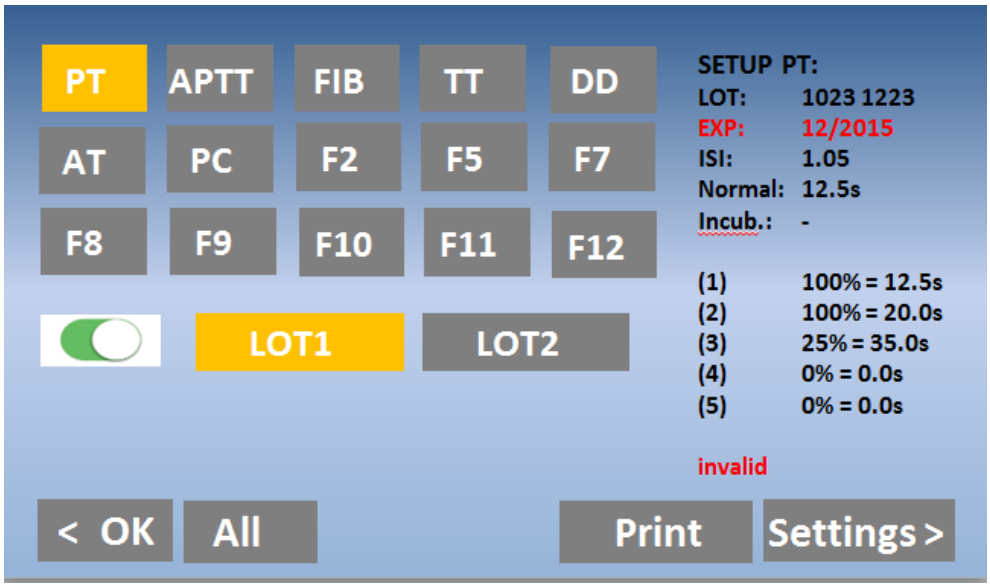
3.3 INTRODUCEREA INFORMAȚIEI DESPRE PACIENT



IMAGINEA 8: INTRODUCEREA NUMĂRULUI DE IDENTIFICARE AL PACIENTULUI

Buton	Titlu	Funcția utilizată
Taste numerice	0-9, C, X	Modificați sau ștergeți NIP
Incrementa	-1 / +1	Măriți NIP. Utilizați posibilitatea de atingere lungă pentru modificarea ușoară.
Hi-Sense	Hi-Sense	Pornește sensibilitatea foarte înaltă de detecție. Util pentru mostre sau rezultate "+++".
Apăsarea lungă	-	Apăsați butonul > 2 sec
Codul de bare mostră	-	Setați numărul de identificare la codul de bare

3.4 ALEGEREA TESTULUI



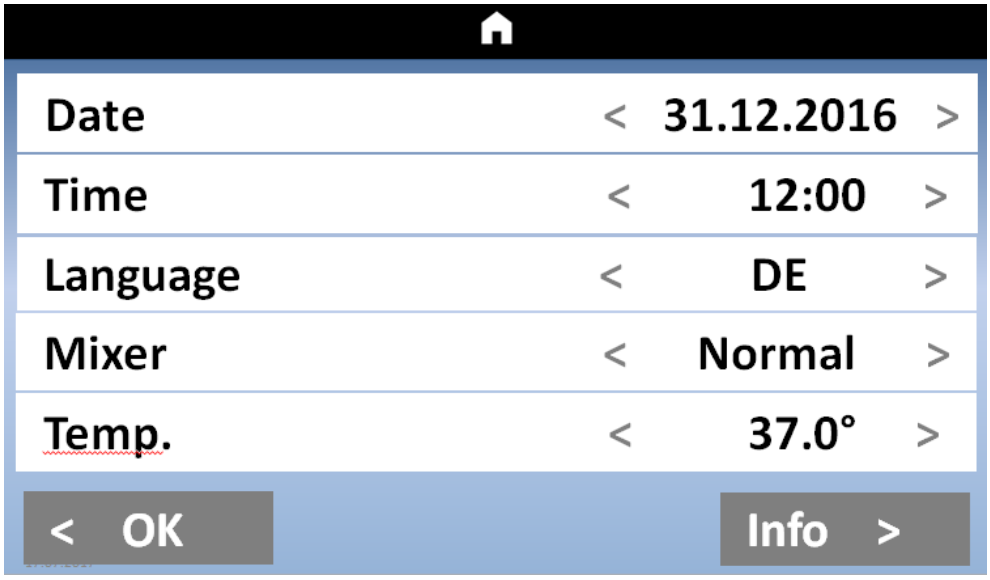
IMAGINEA 9: ALEGEREA TESTULUI LA COATRON X PRO/TOP

Butonul	Titlul	Utilizarea funcției
Butoanele de testare	PT – F12	Alegeți testul
On / Off	On / Off	Activați două LOT-uri pe test (nu sunt disponibile pentru Coatron X Eco)
LOT 1/2	LOT 1/2	Încărcați datele LOT 1 sau 2 de la EEPROM
OK	OK	Confirmați testul pentru canalul curent
Toate	Toate	Confirmați testul pentru toate canalele
Setările	Setările	Schimbați calibrarea testului
Print	Print	Tipăriți setarea testului curent

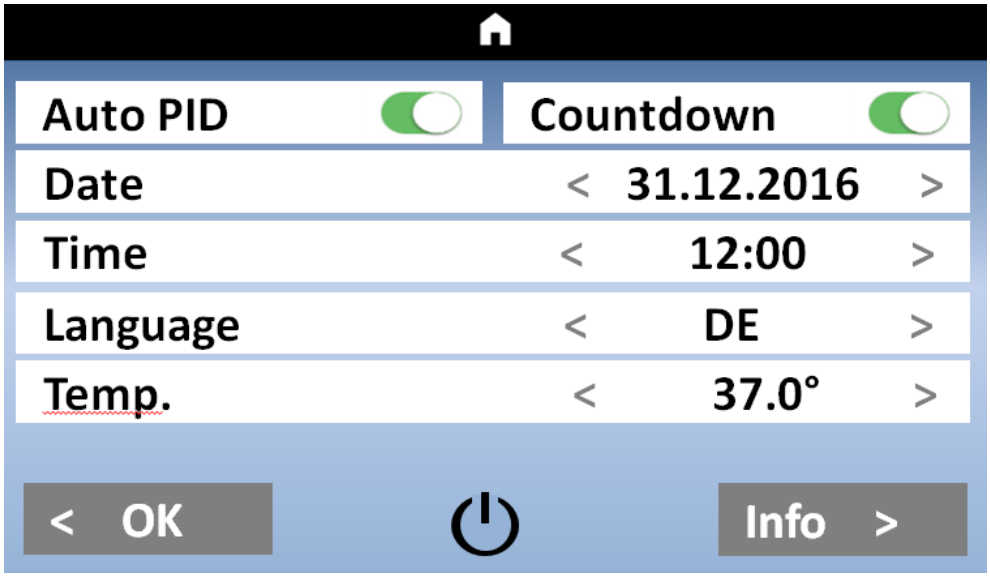
Codul de bare al reagentului	-	Selectați testul curent și lotul. Un semnal sonor lung indică codul de bare sau LOT-ul nevalide.
SETAREA PT	-	Date de calibrare a lotului și testului curent. Valorile roșii indică date nevalide.

3.5 SETĂRILE DE SISTEM

IMAGINEA 10: MENIUL RAPID COATRON X PRO/TOP

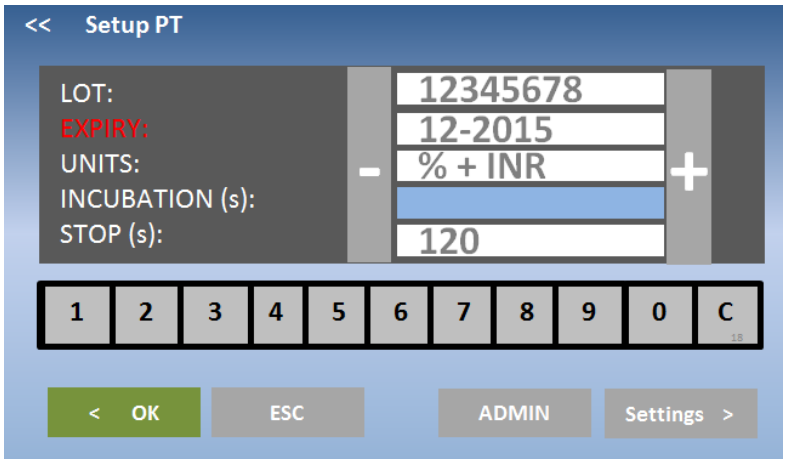


IMAGINEA 11: SETĂRILE DE SISTEM COATRON X PRO/TOP

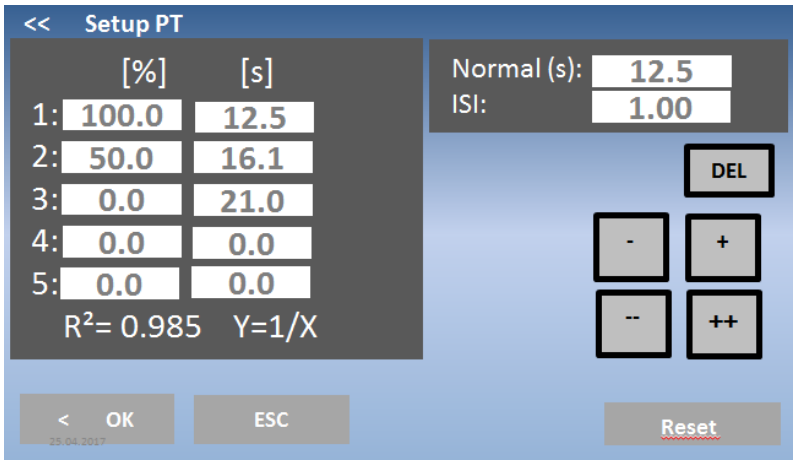


IMAGINEA 12: SETĂRILE DE SISTEM COATRON X ECO

3.6 SETĂRILE TESTULUI

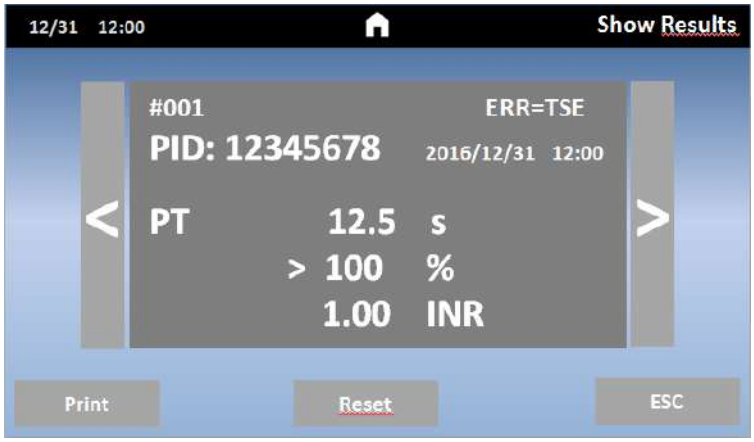


IMAGINEA 13: SETĂRILE TESTULUI 1



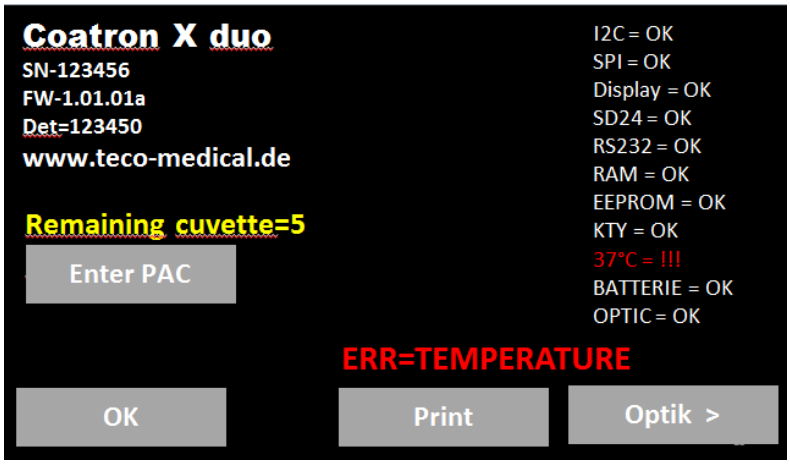
IMAGINEA 2: SETĂRILE TESTULUI 2

3.7 ANALIZAREA REZULTATELOR



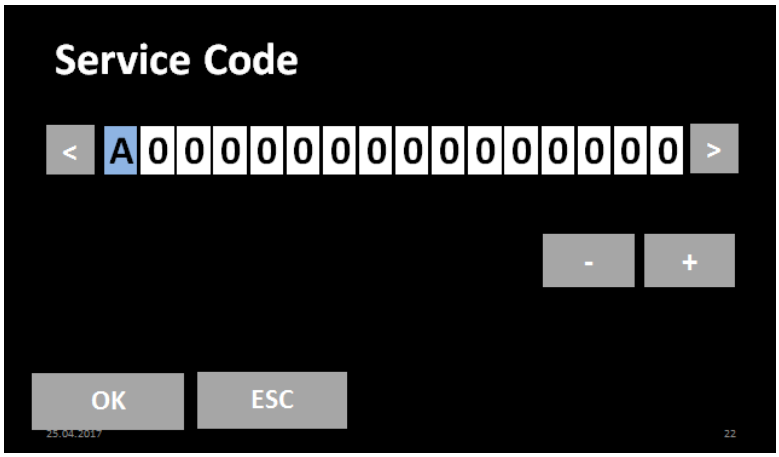
IMAGINEA 15: ANALIZAREA REZULTATELOR COATRON X PRO/TOP

3.8 INFORMAȚIA CU PRIVIRE LA SISTEM



IMAGINEA 16: INFORMAȚIA DESPRE SISTEM

3.9 INFORMAȚIA PRIVIND INTRODUCEREA TICHETELOR



IMAGINEA 17: INFORMAȚIA PRIVIND INTRODUCEREA TICHETULUI

4. TESTE DE COAGULARE DE BAZĂ

4.1 DETERMINAREA PT DIN PLASMĂ

Cum se execută o măsurare PT:
1. Porniți dispozitivul și așteptați aprinderea stării verzi (~ 15 min până la 37 ° C).
2. Reconstituiți reactivul PT și așteptați 30-60 min înainte de pasul următor.
3. Introduceți flaconul PT în blocul de reactiv + bara de agitare și lăsați să incubeze timp de cel puțin 5 min.
4. Schimbați testul canalului 1 în „PT” apăsând pe testul curent.
5. Puneți cuva goală în optică.
6. Introduceți 25 ul de probă în cuvă.
7. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
8. Apăsați „OPTIC-1” și introduceți un numărul de identificare al pacientului sau scanați un cod de bare de probă.
9. Adăugați 50 uL reactiv PT, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
10. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

Activarea multiplă (*cu excepția dispozitivului Coatron ECO*)
1. Deschideți meniul și setați Auto NIP = Pornit.
2. Puneți cuve goale în fiecare canal și pipetați 25 ul de probă pe fiecare cuvă.
3. Apăsați butonul multistart.
4. Adăugați 50 ul PT în fiecare cuvă de la stânga la dreapta.

Cum se calibrează:
1. Reconstituiți calibratorul și așteaptați 15-30 min înainte de a continua cu pasul următor
2. Calibratoare.
Valoarea țintă a calibratorului este starea la certificat. Îmi asum 100% ca exemplu
Soluția IBS, Owrens sau NaCl2 pot fi utilizate ca diluant pentru probă
a. 100%: Pipetați calibrul 100 µl în tubul gol
b. 50%: Pipetați 100 uL 100% calibrator + 100 ul diluant în tubul gol
c. 25%: Pipetați 100 uL 50% calibrator + 100 ul diluant în tubul gol
d. 12,5%: Pipetați 100 uL 25% calibrator + 100 ul diluant în tubul gol
3. Rulați toate cele 4 calibrate ca pacienții și notați timpul de coagulare
(se recomandă efectuarea determinării duble)
4. Introduceți setările PT și introduceți
a. LOT corect, Exp (citiți codul de bare al etichetei flaconului)
b. setați UNITATE la „INR +%”
c. Timp normal de intrare (= 100% rezultat) + ISI (a se vedea flaconul)
d. % Calibrare de intrare

4.2 DETERMINAREA PT DIN SÎNGE CAPILAR

Cum se execută o măsurare PT-B din sângele capilar:
1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 ° C).
2. Schimbați testul în „PTB” apăsând pe testul curent.
3. Reconstituiți PT-B cu componenta-1 (diluant) și așteptați 30-60 min înainte de pasul următor.
4. Adăugați componenta-2 (CaCl2) în PT-B și așteptați din nou timp de 30-60 min înainte de pasul următor.
5. Puneți cuva goală în optică sau în pre-incubare.
6. Introduceți 150 ul de PT-B în cuvă. Cuva trebuie folosită în următorii 10 minute.
7. Închideți flaconul PT-B și păstrați-l în frigider până la următoarea utilizare. Reactivul este stabil timp de 30 de zile.
8. Apăsați „OPTIC-1” și introduceți un NIP (număr de identificare al pacientului) sau scanați un cod de bare de probă.
9. Când „activ” clipește, străpungeți degetul și pipetați 15µL de sânge capilar în cuvă.
10. Măsurarea ar trebui să înceapă. Este important să amestecați în cuvă. Pentru aceasta coborâți pipeta în cuvă și pompați 10-15x în sus și în jos. Terminați amestecarea celei mai recente probe atunci când numărătoarea inversă ajunge la zero.

Cum se calibrează PTB
1. Reconstituie calibratorul cu 1,7mL și așteaptă 15-30min
2. Calibratoare.
Valoarea țintă a calibratorului este starea la certificat. Îmi asum 100% ca exemplu
Soluția IBS, Owrens sau NaCl2 pot fi utilizate ca diluant pentru probă
a. 100%: Pipetați calibrul 100 µl în tubul gol
b. 25%: pipetați 100ul 100% calibrator + diluant 500 ul în tubul gol
3. Rulați toate cele 4 calibrate ca pacienții și notați timpul de coagulare
4. Introduceți setările PTB și introduceți
a. LOT corect, Exp (citiți codul de bare al etichetei flaconului)
b. setați UNITATE la „INR +%”
c. Timp normal de intrare (= 100% rezultat) + ISI (a se vedea flaconul)
d. % Calibrare de intrare

4.3 DETERMINAREA APTT

Cum să executați o măsurare aPTT:
1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 ° C).
2. Schimbați testul în „APTT” apăsând pe testul curent.
3. Puneți CaCl în dispozitiv, lăsați să se incubeze timp de cel puțin 5 min.
4. Puneți cuva goală în optică sau în pre-incubare.
5. Introduceți 25 ul de probă în cuvă.
6. Introduceți 25 uL de reactiv aPTT rece în cuvă.
7. Apăsați „00:00” pentru a porni cronometrul și așteptați 180 de secunde.
8. Cu puțin înainte de sfârșitul incubării, apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare.
9. Adăugați 25 ul de CaCl, când „Active” clipește. Măsurarea va începe automat.
10. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

4.4 DETERMINAREA FIB

Cum să executați o mpsurare FIB:

Metoda nr.1

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 °C).
2. Schimbați testul în „FIB” apăsând pe testul curent.
3. Reconstituiți reactivul FIB și așteptați 30-60 min înainte de pasul următor.
4. Puneți flaconul FIB nu în blocul de reactiv. Temperatura camerei este potrivită.
5. Puneți cuva goală în optică.
6. Introduceți 10 uL de probă în cuvă.
7. Introduceți 90 uL de tampon IBS în cuvă.
8. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
9. Apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare de probă.
10. Adaugați 50 µL de reactiv FIB, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
11. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

Metoda nr.2

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 °C).
2. Schimbați testul în „FIB” apăsând pe testul curent.
3. Reconstituiți reactivul FIB și așteptați 30-60 min înainte de pasul următor.
4. Puneți flaconul FIB nu în blocul de reactiv. Temperatura camerei este potrivită.
5. Pipetați 50 uL de probă prediluată 1: 10 în cuvă (prediluarea se face cu sol. IBS).
6. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
7. Apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare de probă.
8. Adaugați 25 µL de reactiv FIB, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
9. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

Cum să calibrezi FIB

1. Reconstituiți calibratorul și așteaptă 15-30min înainte de a continua cu pasul următor
2. Calibratoare.

Valoarea țintă a calibratorului este starea la certificat. Se presupune ca exemplu 300mg / dL

a. 600 mg / dL: Pipetați 50 pi calibrator + 200 uL tampon IBS în tubul gol
b. 300 mg / dL: Pipetați 50 pi calibrator + 4500 pL tampon IBS în tubul gol
c. 150 mg / dL: Pipetați 50 pi calibrator + 950 uL tampon IBS în tubul gol
d. 75 mg / dL: Pipetați 50 pi calibrator + 1950 uL tampon IBS în tubul gol

3. Rulați toți 4 calibratori

a. Adăugați 50 uL de calibrator în cuvă
b. Adăugați 25 uL de reactiv FIB pentru a începe măsurarea. Scrieți timpii de coagulare pe hârtie sau imprimați

4. Introduceți setările FIB și introduceți

a. LOT corect, Exp
b. setați unitățile la “mg/dL”
c. Introduceți calibrarea mg/dl

5. FUNCȚIILE DE DESERVIRE

5.1 VERIFICAREA OPTICĂ

IMAGINEA 18: VERIFICAREA OPTICĂ

5.2 RAPORTUL DE SISTEM

SYSTEM REPORT

22.08.2017

System:	Coatron X
Version:	V1.01.42
SIN :	01040 01234
PIN:	12345 67890
TEMP:	37.0°C
	50981 (target=50992)

Optic:

Lo	Hi	mA	Qc	
1:2698	28822	5	6	OK
2:2698	29822	6	3	OK
3:2698	30822	7	1	OK
4:2698	29822	6	0	OK

PT=	26
aPTT=	8
FIB=	17
DD=	0
AT=	0
TOTAL	101

Data raportului
denumirea sistemului
versiunea programului
numărul de identificare al sistemului
numărul de identificare al produsului
temperatura opticii și valoarea digitală al senzorului temperaturii
Valorile optice
Lo= LED stins
Hi= LED pornit
mA= energia LED
Qc= zgomotul opticii
OK= nu există eroare
!!= condiție de eroare

Numărarea testelor efectuate

5.3 AJUSTAREA TEMPERATURII

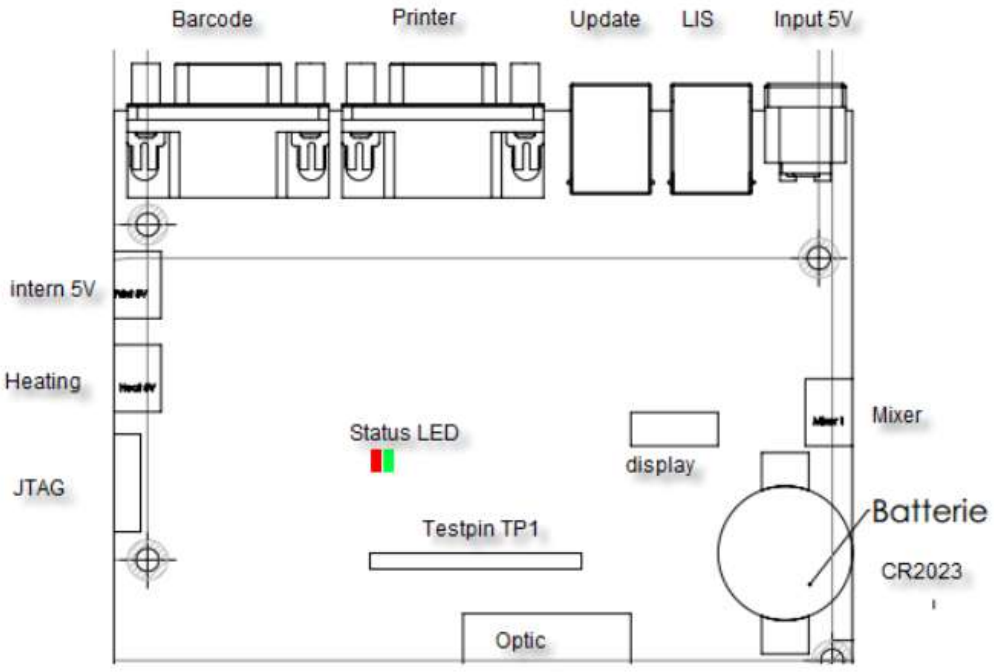
1. Porniți dispozitivul și așteptați aprox. 15min până când sistemul afișează 37 ° C pe ecran.
2. Umpleți un tub / flacon de reactiv cu 2 ml de apă și așezați-l într-o poziție de reactiv. Plasați un termometru digital în tubul de reactiv și lăsați să se încălzească timp de aproximativ 10 minute.
3. Apăsați meniul

Schimbați temperatura sistemului curent la valoarea termometrului. Așteptați 10 min și repetați procedura.

Problemele tipice:

Defecțiunea/Eroarea	**Cauza posibilă**	**Măsurări**
Încălzirea sistemului nu a ajuns la 37°C	Calibrarea senzorului este dincolo de spectrul stabilit	Resetați la implicit din fabrică ca descris în capitolul „Funcție ascunsă"
Sistemul arată 0.00°C	Senzorul a ieșit din diapazon	Temperatura mediului trebuie să fie de 0 – 45°C.
Placa cu senzor sau cu LED optic este defectă	Înlocuți placa LED	

5.4 PREZENTAREA GENERALĂ AL PLĂCII PRICIPALE



Statutul după becul LED:

verde permanent roșu, permanent verde, intermitent roșu, intermitent	= totul este bine = EEPROM eroare = eroarea bateriei = sensor de temperatură/optica nu este conectată

6. FUNCȚIILE ASCUNSE

6.1 RESETAREA LA STAREA DIN FABRICĂ

IMAGINEA 19: ECRANUL DE START

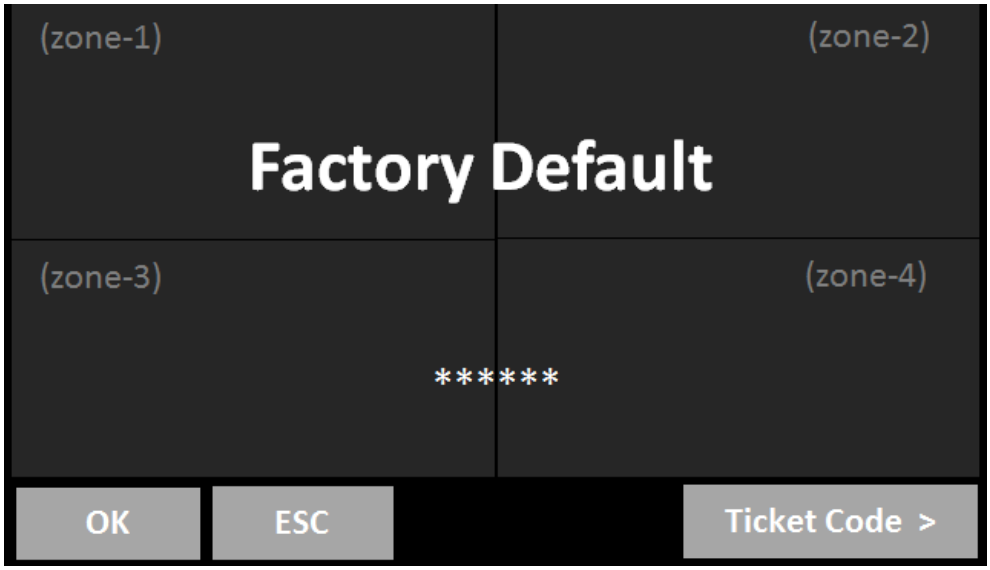
IMAGINEA 20: SETĂRILE IMPLICITE

Apăsați spinerul timp de 3 sec

Cum se resetează calibrarea PT la setările implicite de fabrică:

1. Porniți dispozitivul și treceți la ecranul de pornire
2. Atingeți orice buton de testare
3. Schimbați testul în „PT” și atingeți „Configurare” sau scanați codul de bare al flaconului PT
4. Introduceți LOT, data expirării și selectați Unități în „% + INR”

6.2 LOGAREA ÎN CALITATE DE ADMINISTRATOR



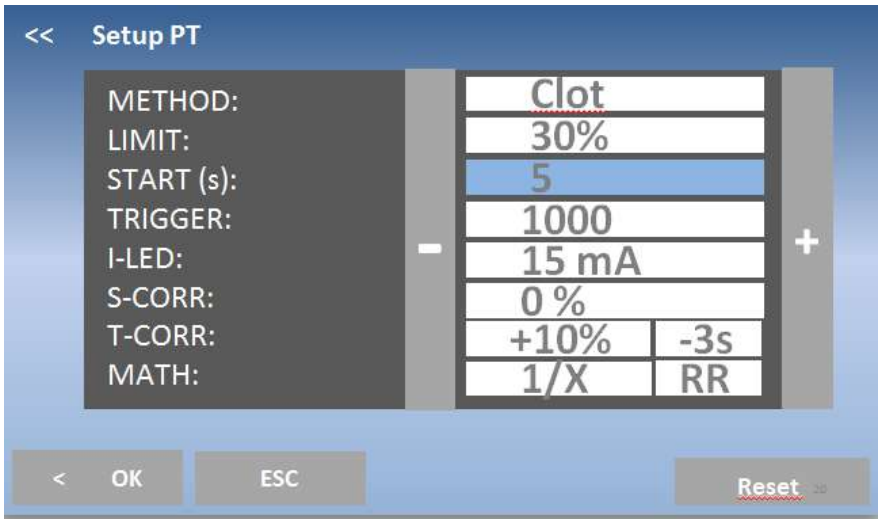
IMAGINEA21 : LOGAREA ÎN CALITATE DE ADMINISTRATOR

1. Ecran de întâmpinare: Apăsați lung pe pictograma filetului
2. Alternativa tactilă: zona 1, 2, 1, 2, 1, 2

Ca admin funcțiile următoare sunt activate:

- Schimbă protocolul de testare (vezi următorul capitol)

6.3 MODIFICAREA PROTOCOLULUI DE TESTARE



IMAGINEA 22: PROTOCOLUL DE TESTARE

7. CURĂȚIREA ȘI MENTENANȚA

7.1 INFORMAȚIA GENERALĂ CU PRIVIRE LA CURĂȚIRE

- Curățați cu o cârpă sau un stick de bumbac fără scame.
- Nu purificați niciodată lichidul în zona optică sau de lucru.
- Păstrați dispozitivul fără praf și umezeală.
- Dacă dispozitivul este murdar cu lichide, îndepărtați murdăria cu o cârpă absorbantă.
- Dacă un lichid a fost vărsat sau pipetat accidental într-un canal de măsurare, deconectați imediat de la sursa de alimentare și curățați canalul de măsurare cu pipeta și o cârpă fără scame. Verificați funcția opticii din meniul DESERVIRE.

Aveți în vedere toate suprafețele și materialele, care ar putea fi în contact cu plasma sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.

Evitați orice contact direct cu decontaminanți sau dezinfectanți.

7.1 CURĂȚIREA

- Folosiți detergent, apă și înălbitor diluat 10% sau decontaminant comercial.
- Curățați și ștergeți toate deversările din jurul zonei de lucru sau ale sistemului de pompare cu ac cu detergent și apă.

7.2 DECONTAMINAREA

- Utilizați înălbitor diluat cu 30% și dezinfectant comercial (de exemplu, Bacillol®AF)
- Decontaminați zona de lucru, zona acului, rafturile pentru pacienți, tastatura, ecranul LCD, carcasele față, imprimanta și sertarele pentru deșeuri

7.3 MENTENANȚA REGULATĂ

• Curățați dispozitivul după fiecare utilizare

• Decontaminați dispozitivul în fiecare săptămână sau înainte de expediere pentru reparare / aruncare

• După 5 ani înlocuiți bateria plăcii de bază (CR2032)

8. ELIMINAREA ERORILOR

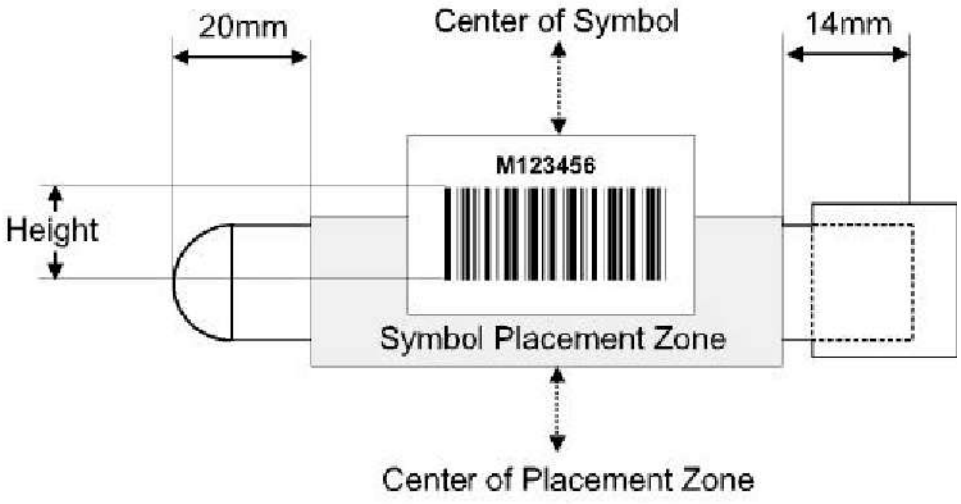
8.1 ERORILE DE MĂSURARE

Eroarea	Cauza posibilă	Măsurarea
Rezultatele marcate "*"	Rezultate ce trec peste limita de calibrare	
Marcat "T"	Temperatura dincolo de 36 – 38°C	
Marcat "E"	Reagentul este expirat	
Marcat "S"	Semnalul optic este foarte scăzut, din cauza turbidității extreme.	Verificați optica Evitați interferențele optice probe lipemice.
Marcat “f”sau "F" (doar testul PT)	Fibrinogen ridicat sau scăzut	Executați testul FIB pentru confirmare
Marcat "X"	Valorile duble deviază cu mai mult de 15%	
Marcat "+++"	Nu a fost observată nici o coagulare cu timpul de măsurare	

- Problemă cu pornirea automată ! (Pipetați spre centru, reduceți sau măriți declanșarea autostartului).

9. ANEXĂ

9.1 GHIDUL CODULUI DE BARE



Specificația etichetei:

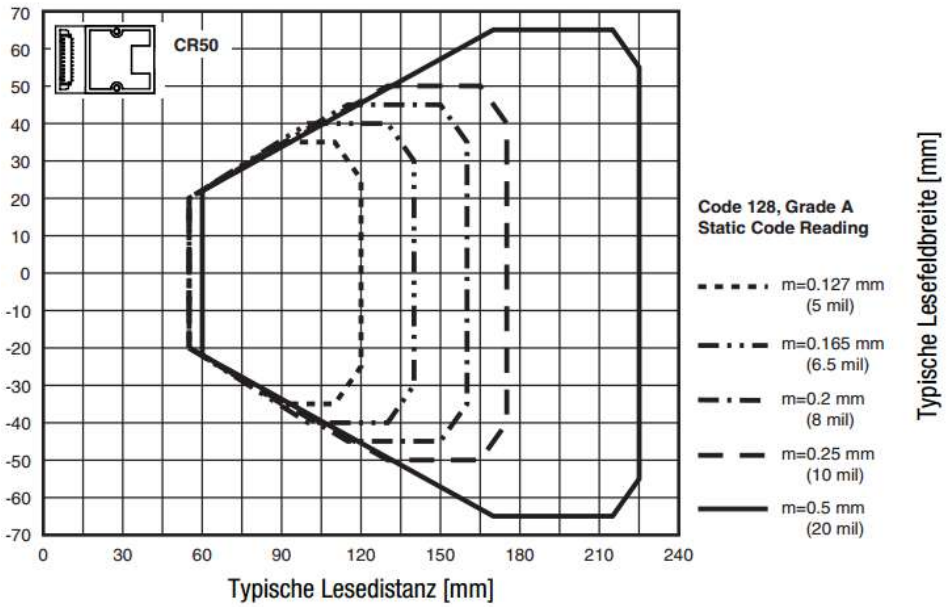
- Lungimea:	50 – 70 mm
- Lățimea:	20 - 30 mm
- Lungimea codului de bare:	40 – 60 mm
- Lățimea codului de bare:	10 - 20 mm
- Zona goală:	> 5mm
- Rezoluția/modul:	5 -20mils (0.2 – 0.5mm)
- Diapazon:	minim 1:2,5 to 1:3 (coduri bidimensionale)
- Calitate	Nivelul A sau B în cpnformitate cu ANSI X3.192 -1990

Coduri acceptate:

- Code 128	3 – 16 caractere
- EAN 128	3 – 13 caractere
- Code 39	4 – 13 caractere
- Code 93	4 – 13 caractere
- 2/5 intercalat	8 - 12 caractere

Câmpul de detecție:

Cea mai bună distanță de etichetă și scaner este de 80 - 120mm



9.2 SPECIFICAȚIILE TEHNICE

Analizator	
Ecran	Ecran tactil TFT 4.3'' 480x272
Sistemul de măsurare	1-4 canale de măsurare independente lungimea de undă a LED-ului 405 nm
Cuvete	Cuva cu un singur canal pentru detectarea optică
Poziții (pre-încălzite)	5 poziții ale reagentului la 36.5 – 37.5 °C 20 poziții ale cuvetelor la 36.5 – 37.5°C
Volumele de reacție	Volumul minim total 75 µl
Aprobări	Analizatorul corespunde cu 98/79/EC (IVDD)
Scanerul codului de bare	
Scaner CCD	Energie maximă = 120mA Perioada de pulsație = 330/s
Clasa B EN 55022:2010 , EN 62471:2008	Lungimea de undă = 617 nm Cea mai bună distanță = 80 -120mm
Codec-ul acceptat	EAN (8,13, 128), Codul (39,93,128), Codabar, Intercalat 2 din 5
Sursa de energie	
Voltajul nominal de intrare	100 – 240VAC , 47-63Hz
Curentul maxim de intrare	0.7A rms
Energia de ieșire	5Vdc , 3.3A
Bateria (placa de bază)	Lithium CR2032 3V
Consumul de energie	max. = 14W așteptare < 0.5W
Dimensiuni	
Dimensiuni (W x D x H)	225 x 150 x 90 mm
Greutatea	1.04 kg (fără sursa de energie)
Condițiile de mediu	
Temperatura de operare	15 - 30 °C
Umiditatea	< 70% umiditate relativă
Ridicarea deasupra nivelului mării	< 3.000m
Liber de praf	Gradul 2
Rezistența la impact	În conformitate cu IEC/EN 61010-1, 8.2.2
Nu sunt permise	Vibrațiile, expunerea la razele directe ale soarelui sau condițiile de aer.
Condițiile de păstrare	0°C - +40°C maxim 12 luni în ambalajul original
Condițiile de transport	0°C - +40°C
Zgomot	
Zgomotul de operare	Maxim 50 dBA

Interfețe	
RS232 (Codul de bare)	Sub-D9, feminin; 9600 Baud/8/1/N; Pin-9 alimentat cu 5V DC. Pentru scanere externe de coduri de bare portabile, imprimante în serie
RS232 (Printer)	Sub-D9 feminin; 9600 Baud/8/1/N; pentru imprimante în serie
USB (Service,Firmware Update)	Tip-B, feminin, 115200 Baud/8/1/N
USB (LIS)	Tip-B, feminin, 115200 Baud/8/1/N; Pentru comunicarea LIS

Date tipice de performanță		
Testul	CV.	Spectrul
PT	<3%	0-30 INR
APTT	<3%	15 – 420 s
FIB	<7%	50-999 mg/dL

TEClot PT-S

CE IVD REF A0230-010, A0230-040, A0230-100,

TECO

Utilizare

Acest produs este utilizat pentru determinarea timpului de protrombină (PT) în plasmă, conform Quick[1,2]. Testul este sensibil la activitatea factorilor de coagulare implicati pe calea "extrinsecă", și anume: II,V,VII,X și fibrinogen și prin urmare este utilizat pentru terapie anticoagulantă orală cu inhibitori ai Vitaminei-K precum Warfarin sau Marcumar. Deasemenea, se utilizează și pentru determinarea cantitativă a factorilor de coagulare implicati pe calea "extrinsecă". PT-ul măsoară timpul de coagulare extrinsecă (activarea factorului VII) a plazmei de testare după adăugarea reagentului PT.

Conținut și Determinări

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

Determinări

Coatron M**	200 Det.	800 Det.	2000 Det.
Coatron A4	100 Det.	400 Det.	1000 Det.
Coatron A6	200 Det.	800 Det.	2000 Det.

*conține un extract din creier de iepure cu Buffer, stabilizatori și Clorură de Calciu.

**Metoda micro (75µl în total)

Preparare

Reconstituiți cu apă de înaltă puritate cu volumul indicat pe eticheta flaconului

A0230-010	A0230-040	A0230-100
2 mL	4 mL	10 mL

Lăsați la temperatura camerei pentru cel puțin 15 minute cu învîrtiri/rotiri ocazionale. Plasați reagentul în aparat și lăsați să se incubeze pentru încă 15 minute. Reactivul sedimentează și trebuie învârtit/rotit înainte de fiecare testare. La aparatele Coatron puteți utiliza o bară de amestecare pentru asta.

Păstrare și Stabilitate

Reagenții nedesfăcuți și păstrați între 2^0-8^0C, sunt stabili pînă la data expirării indicate pe ambalaj,. Reagenții deschiși deja, sunt stabili :

	2^0-8^0C	**20-25^0C**	**37^0C**
PT reagent	5 zile	36 ore	8 ore

Măsuri de precauție

Evitați contactul cu pielea și ochii. Purtați haine de protecție adecvate. Eliminați componentele în conformitate cu reglementările locale pentru materialele infecțioase. Toate componentele sunt verificate pentru HIV, VHB, VHC. Cu toate acestea, produsele din sângele uman ar trebui considerate potențial infecțioase.

Colectarea și depozitarea probei [4]

1. Obțineți sîngele venos prin puncție curată a venei.
2. Amestecați imediat 9 părți de sînge cu 1 parte de 3,2% de Citrat de Na (0.105M) și amestecați bine.
3. Centrifugați specimenul la 1500g pentru 10 min (trombocite < 10000/µL).
4. Separați plazma după centrifugare și depozitați în tuburi de sticlă siliconizată.
5. Utilizați plazma în timp de 4 ore sau înghețați și dezghețați doar înainte de utilizare.

Stabilitatea plazmei: 4 ore la 18-26°C, 8 ore la 2-8°, 30 zile la -20°C, 6 luni la -70°C

Procedura

A. Metoda automată: 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. Metoda manuală:
   1. Incubați reagentul PT la 37°C pentru cel puțin 10 minute
   2. Pipetați **25 µl** din specimen în cuveta pentru testare. Incubați la 37°C pentru 1-2 min
   3. Adăugați **50 µl** de reagent PT (37°C) și începeți simultan testul.
   4. Înregistrați/măsurați în secunde timpul de coagulare.

Rezultate așteptate

Secunde tipice : 11-18 sec

Intervalul normal: 70 - 130% 0.85 – 1.15 INR

Oricum, rezultatele sunt influiențate de aparate, tehnică, calibrare etc. Se recomandă ca fiecare laborator să-și stabilească propriul interval, specific aparatelor utilizate.

Standardizare și Calibrare

Rezultatul PT este exprimat în secunde sau activitate (% Quick) sau INR (International Normalised Ratio).

Rezultatele INR:

-au fost calculate din timpul normal și valoarea ISI (international sensitivity index/ indicele internațional de sensibilitate). Primul este obținut prin testarea plazmei proaspete a unui grup de indivizi sănătoși. Valoarea ISI este stabilită în certificatul de analiză specific fiecarui lot.

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

Rezultatele % activității (Quick):

-au fost calculate dintr-o curbă de calibrare, care a fost pregătită după plasma de referință (e.g. **TECAL N**) și diluări în soluții saline ca 0.9% de NaCl2 sau TECLOT IBS buffer. Sunt recomandate cel puțin 3 sau mai multe pucte de calibrare . Curba de calibrare trebuie confirmată cu plasma de control cu interval normal și patologic.

% din normal	**100%***	**50%**	**25%**	**12,5%****
diluat în soluție salină	Fără diluție	1+1	1+3	1+7

*media de la cel puțin 21 de indivizi sănătoși este definită ca 100%[5]

**diluția de 12.5% poate cauza rezultate "+++" în unele cazuri, pentru că nivelul de diluție al fibrinogenului este prea mare pentru detecție optică.

Controlul Calității

TEControl sau altă plasmă de control comercială trebuie utilizată pentru controlul calității performanței la o frecvență în conformitate cu practicele bune de laborator (GLP). TEControl poate fi înghețat o singură dată după reconstituire. 120-150 µl păstrat închis în tuburi de polipropilen la -20°C , este stabil timp de 30 zile.

Restricții/ Limitări

O mare grijă și atenție trebuie de avut la factorii care pot părea nesemnificativi.

A. Colectarea probei. Evitați:
    1. Folosiți doar tuburi de plastic sau sticlă siliconizată.
    2. Amestecarea întîrziată a sîngelui cu anticoagulant.
    3. Contaminarea cu tromboplastină tisulară.
    4. Raportul greșit de sînge cu anticoagulant.
    5. Probele hemolizate, icterice sau lipemice pot interfera sistemele optice.
B. Tehnici de Laborator:
    1. Efectuați testul la 37°C.
    2. Utilizați doar apă cu puritate înaltă.
    3. pH-ul optim este 7.0-7.5.
    4. Valoarea ISI nu e constantă în primile 30 min după reconstituire.
    5. Reagentul face sedimente , de aceea trebuie de agitat înainte de fiecare testare.

Caracteristici de performanță

Performanțe tipice pe aparatul Coatron M4:

Precision:	CV% (în timpul testării)	CV% (între testări)
Normal control	< 3,0	< 5,0
Abnormal control	< 3,0	< 5,0

Garanție

Acest produs este garantat doar dacă se utilizează în conformitate cu informațiile de pe eticheta proprie și din instrucțiune. TECO nu acordă garanție dacă produsul este utilizat în alt scop și în niciun caz TECO nu va fi răspunzător pentru daunele care rezultă din garanția expresă menționată mai sus.

Referințe:

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

TECO

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

Utilizare

Acest produs are scopul de a determina Timpului de Tromboplastină Parțial Activat (APTT) folosind silicat în calitate de activator. Determinarea de APTT se folosește pentru o evaluare "globală" a "căii intrinsece" și pentru detectarea deficiențelor de coagulare intrinsecă a factorilor VIII, IX, XI, XII și Fletcher Factor, precum și pentru monitorizarae terapiei cu anticoagulant heparină sau alte metode de coagulare unde este necesar reagent APTT[1,2]. Reagentul APTT din kit conține fosfolipide și silicat pentru a asigura o consistență și stabilitate înaltă a produsului[3]. Reagentul APTT este insensibil la anticoagulant Lupus. Reagenții insensibili la anticoagulant Lupus dau un randament mai de încredere a rezultatelor testării factorilor, decît reagenții sensibili la inhibitori Lupus[4]. Timpii prelungiți de coagulare pot fi observați în următoarele situații: deficiență a factorilor de coagulare intrinsecă, prezența heparinei, în boli de ficat, deficiență de vitamina K sau alți anticoagulanți care afectează calea intrinsecă de coagulare.

Conținut și Determinări

Produs	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
CaCl2 0.025M**	5x5 mL	5x10 mL	-	-

Determinări

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.

* Reagentul APTT-S conține silicat coloidal cu fosfolipide, buffer și conservanți.

** CaCl2 conține azida de sodiu.

***Metoda Micro (75µL în total)

Preparare

Componentele kitului sunt gata de utilizare. Permite la $CaCl_2$ să se preîncălzească timp de 15 minute la temperatura de 37 °C și amestecă atent reagentul înainte de utilizare.

Păstrare și Stabilitate

Reagenții care nu au fost deschiși sunt stabili pînă la data expirării indicate pe ambalaj, păstrați la temperatura de 2°-8°C. Reagenții deschiși deja se păstrează:

	2-8 ºC	20-25 ºC	37 ºC
APTT-S Reagent	30 zile	8 zile	8 ore

Măsuri de precauție

Evitați contactul cu pielea și ochii. Purtați haine de protecție adecvate. Eliminați componentele în conformitate cu reglementările locale pentru materialele infecțioase. Toate componentele sunt verificate pentru HIV, HBV, HCV. Cu toate acestea, produsele din sângele uman ar trebui considerate potențial infecțioase.

Colectarea și păstrarea probelor [5]

1. Obțineți sînge venos printr-o puncție curată a venei.
2. Amestecați imediat 9 părți de sînge cu 1 parte de 3.2% sodium citrate (0.105M) și amestecați bine.
3. Centrifugați proba la 1500g timp de 10 minute (trombocite < 10000/µL).
4. Separați plasma după centrifugare și păstrați în plastic sau tuburi de sticlă siliconată.
5. Folosiți plazma în timp de 4 ore sau depozitați/păstrați înghețat și dezghețați numai înainte de folosire.

Stabilitatea plazmei: 4 ore la 18-26°C, 8 ore la 2-8°, 14 zile la -20°C, 6 luni la -70°C

Procedura

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. Metoda manuală: Coatron M

1. Preîncălziți CaCl2 (0.025M) la 37°C pentru cel puțin 10 minute.

2. Pipetați 25 µl de probă/specimen într-o cuvetă pentru testare. Preîncălziți la 37°C pentru 1-2 minute.

3. Adăugați 25 µl de reagent APTT-S și incubați pentru exact 3 minute la temperatura de 37°C.

4. Adăugați 25 µl de CaCl2 (0.025M) și simultan începeți testul.

5. Măsurați timpul de coagulare în secunde.

Rezultate așteptate

Rezultatele tipice normale sunt de 23-47 sec. Oricum, rezultatele sunt influiențate de metoda de detecție a coagulării și poate varia de la laborator la laborator.Este recomandat ca fiecare laborator să-și stabilească propriul interval normal specific pe aparatul utilizat.

Controlul Calității

TEControl sau altă plasmă de control comercială trebuie utilizată pentru controlul calității performanței la o frecvență în conformitate cu practicele bune de laborator (GLP). TEControl poate fi înghețat o singură dată după reconstituire. 120-150 µl păstrat închis în tuburi de polipropilen la -20°C , este stabil timp de 30 zile.

Limitări / Restricții

A. Colectarea probei.EVITAȚI:

1. Folosiți doar tuburi de plastic sau sticlă siliconizată.

2. Întîrzierea amestecării sîngelui cu anticoagulant.

3. Contaminarea cu tromboplastină tisulară.

4. Raportul greșit dintre sînge și anticoagulant.

5. Probele hemolizate, icterice sau lipemice pot interfera sistemele optice.

B . Tehnici de Laborator:

1. Efectuați testul la 37°C.
2. Utilizați doar apă cu puritate înaltă.
3. pH-ul optim este 7.0-7.5.

Caracteristici de performanță:

Performanțe tipice pe aparatul Coatron M4:

Precizia	CV%(în timpul testării)	CV%(între testări)
QC control	< 3,0	< 5,0

Sensibilitatea Factorilor și Heparinei:

	APTT timp de coagulare (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 timp de coagulare (s)	35	70	180

Garanție

Acest produs este garantat doar dacă se utilizează în conformitate cu informațiile de pe eticheta proprie și din instrucțiune. TECO nu acordă garanție dacă produsul este utilizat în alt scop și în niciun caz TECO nu va fi răspunzător pentru daunele care rezultă din garanția expresă menționată mai sus.

Referințe

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

TEClot FIB TECO

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

Utilizare

TEClot FIB este utilizat pentru determinarea cantitativă a fibrinogenului în plasma umană, conform tehnicii dezvoltată de Clauss[1]. Nivelul de fibrinogen poate crește ca rezultat al inflamării, sarcinii sau utilizarea contraceptivelor orale[2]. Nivelul scăzut de fibrinogen poate fi identificat în situații concrete precum boli de ficat sau DIC (Coagulare intravasculară diseminată). Deficiențele congenitale includ afibrinogenaemia (nici un fibrinogen detectabil), hypofibrinogenaemia (<1 mg/ml) și dysfibrinogenaemia (molecula anormală de fibrinogen).

Conținut și preparare

Product	TEClot FIB Kit-10	TEClot FIB Kit-25	TEClot FIB	TEClot FIB
Cat.No.	A0501-010	A0501-025	A0511-020	A0511-050
Reactivul de trombină	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	-	-

Determinări

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 .

*Metoda micro (75µL în total)

1. Reactivul de trombină:
   Conține trombină de bovină (~80NIH) cu stabilizatori.
   REF: A0501-010/A0511-020: reconstituiți cu 2 ml de apă purificată.
   REF: A0501-025/A0511-050: reconstituiți cu 5 ml de apă purificată.
2. IBS Buffer: Gata de utilizare. Conține soluție salină tamponată Imidazol.
3. TECal Normal: reconstituiți cu 1 ml de apă purificată. Conține plasma umană citrată.
4. TEControl A: reconstituiți cu 1 ml de apă purificată. Conține plasma umană citrată.

Rotiți ușor după reconstituire și lăsați timp de 15 minute la temperatura camerei. Amestecați bine înainte de utilizare. Nu agitați/ scuturați.

Păstrare și stabilitate

Reagenții care nu au fost deschiși sunt stabili pînă la data expirării indicate pe ambalaj, păstrați la temperatura de 2°-8°C. Reagenții deschiși deja se păstrează:

Reactivul de trombină*	2-8 ºC	15-25 ºC	37 ºC
	12 zile	5 zile	24 ore
TEControl sau Plasma	2-8 ºC	15-25 ºC	-20 ºC
	8 ore	4 ore	30 zile

*Reactivul trebuie de protejat razele ultraviolete și evaporație.

Măsuri de precauție

Evitați contactul cu pielea și ochii. Purtați haine de protecție adecvate. Eliminați componentele în conformitate cu reglementările locale pentru materialele infecțioase. Toate componentele sunt verificate pentru HIV, HBV, HCV. Cu toate acestea, produsele din sângele uman ar trebui considerate potențial infecțioase.

Colectarea și păstrarea probelor [3]

1. Obțineți sânge venos printr-o puncție curată a venei.
2. Amestecați imediat 9 părți de sânge cu 1 parte de 3.2% sodium citrate (0.105M) și amestecați bine.
3. Centrifugați proba la 1500g timp de 10 minute (trombocite < 10000/µL).
4. Separați plasma după centrifugare și păstrați în plastic sau tuburi de sticlă siliconată.
5. Folosiți plazma în timp de 4 ore sau depozitați/păstrați înghețat și dezghețați numai înainte de folosire.

Procedura

A. Metoda automată 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. Metoda manuală Coatron M

1. Prepararea diluțiilor pentru Standard, Control și Pacient.

Diluția Standard	Plazma	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
Pacient sau Control	100µL Plasma	900µL

2. Pipetați 50 µl de standard diluat sau plazma pacientului (1:10) într-o cuvetă pentru testare. Preîncălziți la 37°C timp de 1-2 minute.
3. Adăugați 25 µl de reactiv de trombină și simultan începeți testul.
   Pentru alte aparate , consultați manualul cu instrucțiuni specifice mai detaliate.

Calibrare

Ca referință trebuie de utilizat TECal Normal sau altă Plasma standard comercială preparată în care fibrinogenul a fost determinat. (200-300mg/dL). Reprezintă grafic timpul de coagulare obținut cu fiecare din diluțiile standard ale fibrinogenului pe axa-y , opus concentrației de fibrinogen (mg/dL) pe axa-x utilizînd hîrtia grafică log-log. Linia cea mai potrivită trebuie de determinat prin analiza regresiei liniare. Fibrinogenul din probele de plasmă poate fi determinat prin interpolare din curba de calibrare.

Rezultate asteptate

Rezultatele normale tipice sunt 180-450 mg/dL[4,5]. Oricum , rezultatele sunt influiențate de metoda de detecție a coagulării și poate varia de la laborator la laborator. Este recomandat ca fiecare laborator să-și stabilească propriul interval normal specific aparatului utilizat.

Controlul Calității

Pentru un control de încredere al calității performanței , trebuie utilizată TEControl sau altă plasmă de control comercială la o frecvență în conformitate cu practicele bune de laborator (GLP). TEControl poate fi înghețat o singură dată după reconstituire. 120-150 µl păstrat închis în tuburi de polipropilen la -20°C , este stabil timp de 30 zile.

Limitări / Restricții

A. Colectarea probei.EVITAȚI:

1. Folosiți doar tuburi de plastic sau sticlă siliconizată.

2. Întîrzierea amestecării sîngelui cu anticoagulant.

3. Contaminarea cu tromboplastină tisulară.

4. Raportul greșit dintre sînge și anticoagulant.

5. Probele hemolizate, icterice sau lipemice pot interfera sistemele optice.

B . Tehnici de Laborator:

1. Efectuați testul la 37°C.
2. Utilizați doar apă cu puritate înaltă.
3. pH-ul optim este 7.0-7.5.

Caracteristici de performanță:

Precizia	CV%(în timpul testării)	CV%(între testări)
Normal control	< 5.0	< 5.0
Abnormal control	< 5.0	< 10.0

(Performanțe tipice pentru aparatul Coatron M4)

Garanție

Acest produs este garantat doar dacă se utilizează în conformitate cu informațiile de pe eticheta proprie și din instrucțiune. TECO nu acordă garanție dacă produsul este utilizat în alt scop și în niciun caz TECO nu va fi răspunzător pentru daunele care rezultă din garanția expresă menționată mai sus.

Referințe

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

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

TEClot APTT-S

CE | IVD | REF A0320-050

Intended Use
Clotting test for quantitative determination of the Activated Partial Thromboplastin Time (APTT) in citrated human plasma using silicate as contact activator for factor XII. Intended to be used by professional laboratory personnel using coagulation analysers. The determination of the APTT is used for the global evaluation of the intrinsic pathway and detecting deficiencies of the intrinsic coagulation factors VIII, IX, XI, XII, and Fletcher Factor or other coagulation methods where an APTT reagent is required[1,2].

The APTT reagent in the kit contains phospholipids and silica to ensure a highly consistent and stable 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 or other anticoagulants, which affect the intrinsic pathway and in liver diseases.

Contents

Product	TEClot aPTT-S
REF	A0320-050
aPTT-S reagent	10x5 mL
Determinations*	2000

*Micro method (75µL in total)

APTT-S reagent contains colloidal silicate with phospholipids, buffer and preservatives.

Recommended additional material (not included in package)

Auxilary reagents	A0350-050 Calcium Chloride 0.025M, 10 x 5mL
Calibration	not required
Quality Control	P6001-010 TEControl N, 10 x 1mL P6101-010 TEControl A, 10 x 1mL

Preparation
Ready to use. Swirl APTT reagent gently prior usage

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

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

Precautions
The reagent contains sodium azide (less than 0.1%) to prevent microbial growth. Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.

Specimen collection and storage[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
See application book of device

B. Manual Method: Coatron X
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.

C. Interfering substances
1. Bilirubin 40mg/dL
2. Haemoglobin 1000 mg/dL

Performance Characteristics

Typical performance on instrument Coatron X

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

Factor & Heparin sensitivity:

	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

TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1 - 84088 Neufahrn i.NB - Germany

TEClot APTT-S

CE | IVD | REF A0320-050

Verwendungszweck

Dieses Produkt ist bestimmt für die quantitative Bestimmung der aktivierten partiellen Thromboplastinzeit (APTT) in humanen Citratplasma mit Hilfe von Silikat als Kontaktaktivator für Faktor XII. Die Anwendung ist bestimmt für medizinisches Fachpersonal und benötigt einen Gerinnungsanalyser.

Die Bestimmung der APTT dient der globalen Auswertung des intrinsischen Gerinnungssystems, sowohl zum Nachweis von Mängeln bei den intrinsischen Koagulationsfaktoren VIII, IX, XI, XII und Fletcher Faktor oder anderer Koagulationsmethoden, bei denen ein APTT - Reagenz benötigt wird.[1,2]

Das APTT Reagenz in diesem Kit enthält Phospholipide und Silizium, um ein sehr widerstandsfähiges und stabiles Produkt zu gewährleisten[3]. Das Reagenz reagiert nicht auf Lupus Antikoagulanz und liefert daher verlässlichere Ergebnisse bei Faktorbestimmungen[4]. Verlängerte Gerinnungszeiten können bei den folgenden Situationen beobachtet werden: Mangel an intrinsischen Koagulationsfaktoren, Vorhandensein von Heparin oder andere Antikoagulantien, die das intrinsische System beeinflussen und bei Lebererkrankungen.

Inhalt

Produkt	TEClot aPTT-S
REF	A0320-050
aPTT-S Reagenz	10x5 mL
Bestimmungen*	2000

*Micro Methode (75µL insgesamt)

Das APTT-S Reagenz enthält kolloidales Silikat mit Phospholipiden, Puffer und Konservierungsstoffe.

Zusätzlich notwendige Reagenzien (nicht in der Packung vorhanden)

Hilfsreagenzien	A0350-050 Calcium Chloride 0.025M, 10 x 5mL
Kalibration	Nicht notwendig
Qualitätskontrolle	P6001-010 TEControl N, 10 x 1mL P6101-010 TEControl A, 10 x 1mL

Vorbereitung

Das Reagenz ist gebrauchsfertig und muss vor dem Gebrauch leicht aufgemischt werden.

Lagerung und Stabilität

Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum stabil. Geöffnetes Reagenz:

	2-8 °C	20-25 °C	37°C
APTT-S Reagenz	30 Tage	8 Tage	8 Stunden

Vorsichtsmaßnahmen

Das Reagenz beinhaltet Natriumazid (< 0.1%). Augen und Hautkontakt vermeiden. Geeignete Schutzkleidung tragen. Abfall gemäß lokaler Bestimmungen für infektiöse Materialien entsorgen.

Probenentnahme und Lagerung [5]

1. Venöses Blut mittels Venenpunktur unter sauberen Bedingungen entnehmen.
2. Sofort 9 Teile Blut mit einem Teil 3,2% Natriumzitrat (0,105M) gut mischen.
3. Probe bei 1500g 10Minuten lang zentrifugieren (Thrombozyten <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.

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

Verfahren

A. Automatenmethode: Coatron A
Siehe Applikationsbuch des Gerätes

B. Manuelle Methode: Coatron X

1. Kalciumchlorid (0,025M) mind. 10 Minuten lang bei 37°C erwärmen.
2. **25µl Probe** in eine Küvette pipettieren. Bei 37°C für 1-2 min vorwärmen.
3. **25µl APTT-S** Reagenz hinzufügen und für genau **3 min bei 37°C inkubieren**
4. **25µl $CaCl_2$** (0,025M) hinzufügen und gleichzeitig Test starten.
5. Gerinnungszeit in Sekunden notieren.

Erwartete Ergebnisse

Typische normale Ergebnisse liegen bei 27-42 Sekunden. Jedoch sind die Ergebnisse von der verwendeten Methode der Gerinnungsbestimmung abhängig und können in verschiedenen Labors unterschiedlich ausfallen. Jedem Labor wird empfohlen, eine eigene Ergebnisreihe und den Normalbereich mit dem verwendeten Gerät zu erstellen.

Qualitätskontrolle

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

Vorschriften

A. Probenvorbereitung. Achten Sie auf:
1. nur Plastikröhrchen oder silikonisiertes Glas verwenden
2. verzögertes Mischen von Blut mit 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

C. Interferenzen
1. Bilirubin: kein Effekt unter 40mg/dL
2. Hämoglobin: kein Effekt unter 1000mg/dL

Leistungsdaten

Typische Leistungsdaten beim Gerät Coatron X

Präzision:	VK% (Einzellauf)	CV% (Mehrfachlauf)
QC control	< 3,0	< 5,0

Faktor & Heparin Empfindlichkeit:

	APTT Gerinnungszeit (s)		
Faktor (%)	F VIII	F IX	F XI
< 1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	358

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

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

Garantie

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

Referenzen

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol 36, 212-219 (1961).*
2. Triplett DA, 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

Erklärung der Symbole:

Verfallsdatum	IVD	In-Vitro Diagnostik	Biologische Gefahr	REF	Katalog-Nummer	Begleitpapiere beachten

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

TECO Medical Instruents Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn i.NB Germany

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

CE | 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

STATEMENT

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

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

Date: January 3, 2023

Signature: 

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 104507 0001 Rev. 03

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

Certification Mark:

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

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

Report No.: SH22743A01

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

Date, 2022-09-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 104507 0001 Rev. 03

Applied Standard(s):

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

Facility(ies):

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

Address holder for registration only

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

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

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

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

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

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

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

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

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

EC Certificate

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

No. V1 104507 0003 Rev. 06

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

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

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

Report no.: SH22743EXT01

Valid from: 2022-05-04
Valid until: 2025-05-26

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Product Service

EC Certificate

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

No. V1 104507 0003 Rev. 06

Model(s):

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

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

No. V1 104507 0003 Rev. 06

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

Facility(ies):

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

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

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

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

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

Declaration of Conformity

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

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

Mission® Urinalysis Reagent Strips (U031-XX1)

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

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

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

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

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

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

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

November 11th 2016

CERTIFICATION LETTER

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

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

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

Sincerely

ACON LABORATORIES, INC. S.A.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc.
jalvarenga@aconlabs.com
+1 858 875 8085

Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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

ACON®

Global Diagnostics for Local Markets™

Urinalysis Reagent Strips

Simple and Accurate

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

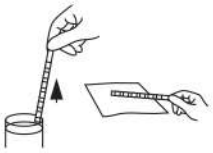
Flexible

- Compatible for visual and analyzer reading
- Over 35 different combinations available

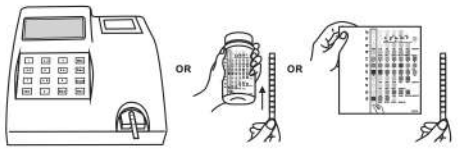
Multiple Packaging Options and Long Shelf Life

- Canister Packaging
  - Available in 25, 50 and 100 strips per canister
  - 2 year shelf life for unopened canisters which 150 strips per kit without MA/CRE Combo offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging
  - Individually packaged strips available in kit of 3 or 6 strips for visual reading only (includes 1 color chart)
  - Unique packaging maintains 2 year shelf life for all strips in the kit compared to 3 months for remaining strips in an opened canister

Step 1: Immerse strip into urine



Step 2: Remove excess urine



Step 3: Obtain results by analyzer or visual reading

No.	Catalog No.	No. of Parameters	Type of Strip§		Reading Availability				Parameters													
			Visual Reading	Analyzer Reading	Visual	U120	U120 Ultra	U500	ASC	GLU	BIL	KET	SG	BLO	PH	PRO	URO	NIT	LEU	ALB	CRE	CA
1	U031-141	14	14C√		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*	*	*	
2	U031-131	13	13CE√		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*	*	*	
3	U031-111	11	11A√†		Yes	Yes	Yes	Yes	*	*	*	*	*	*	*	*	*	*	*			
4	U031-101	10	10U√x		Yes	Yes	Yes	Yes		*	*	*	*	*	*	*	*	*	*			
5	U031-191	9	9U√x		Yes	Yes	Yes	Yes		*	*	*	*	*	*	*	*	*				
6	U031-081	8	8U√x		Yes	Yes	Yes	Yes		*	*	*		*	*	*	*	*				
7			8N√x		Yes	Yes	Yes	Yes		*		*	*	*	*	*		*	*			
8			8S√x		Yes	Yes	No	Yes		*			*	*	*	*	*	*	*			
9			*8K*√x		Yes	Yes	No	Yes		*	*	*			*	*	*	*	*			
10	U031-071	7	7N√x		Yes	Yes	Yes	Yes		*		*		*	*	*		*	*			
11	U031-061	6	6N√x	6NE√x	Yes	Yes	No	Yes		*				*	*	*		*	*			
12			6U√x	6UE√x	Yes	Yes	No	Yes			*		*	*		*	*	*				
13	U031-051	5	5B√x	5BE√x	Yes	Yes	No	No		*		*		*	*	*						
14			5N√x	5NE√x	Yes	Yes	Yes	No		*				*		*		*	*			
15			*5S*√x	*5SE*√x	Yes	Yes	No	No		*			*	*	*	*						
16			*5U*√x	*5UE*√x	Yes	Yes	No	No			*			*			*	*	*			
17	U031-041	4	4P√x	4PE√x	Yes	Yes	Yes	Yes		*						*		*	*			
18			4S√x	4SE√x	Yes	Yes	Yes	Yes		*			*		*	*						
19			4B√x	4BE√x	Yes	Yes	No	No		*				*	*	*						
20			4K√x	4KE√x	Yes	Yes	Yes	Yes		*		*			*	*						
21			4G√x	4GE√x	Yes	Yes	No	No		*				*		*			*			
22			4N√x	4NE√x	Yes	Yes	No	Yes						*		*		*	*			
23	U031-031	3	3P√x	3PE√x	Yes	Yes	Yes	Yes		*					*	*						
24			3K√x	3KE√x	Yes	Yes	Yes	Yes		*		*				*						
25			*3G*√x	*3GE*√x	Yes	Yes	No	Yes		*		*			*							
26			3N√x	3NE√x	Yes	Yes	No	Yes						*				*	*			
27	U031-021	2	2G√x	2GE√x	Yes	Yes	Yes	Yes		*						*						
28			2K√x	2KE√x	Yes	Yes	Yes	Yes		*		*										
29			2N√x	2NE√x	Yes	Yes	Yes	Yes										*	*			
30			2B√x	2BE√x	Yes	Yes	No	Yes						*					*			
31			2U√x	2UE√x	Yes	Yes	No	Yes			*						*					
32			*2S*√x	*2SE*√x	Yes	Yes	No	Yes					*		*							
33			2C√	2CE√	Yes	Yes	Yes	Yes												*	*	
34	U031-011	1	*1B*√x	*1BE*√x	Yes	Yes	No	No						*								
35			1P√x	1PE√x	Yes	Yes	No	No							*							
36			1G√x	1GE√x	Yes	Yes	Yes	No		*												
37			1K√x	1KE√x	Yes	Yes	No	No				*										
38			1R√x	1RE√x	Yes	Yes	No	No								*						

§Type of Strip:
Visual Strip Size: 1-6 Parameters: 80 mm x 5 mm; 7-14 Parameters: 108 mm x 5 mm
U120/U500 Strip Size: 1-14 Parameters: 108 mm x 5 mm
"E" means extended strip length for 1-6 Parameters and exclusive strip length for 13 Parameter
Default Type of Strip (U120/U500): 11A, 10U, 9U and 8N
Standard Black Canisters : Available for 25, 50 and 100 strips; 150 strips per kit without MA/CRE Combo
Pouch: Single-strip pouch available in kit of 3 or 6 for visual reading only

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x FDA 510(k) Cleared and CLIA Waived

U120 Urine Analyzer

Accurate
- Up to 120 tests/hour in Continuous Test Option
- Test categories include Routine, STAT and QC
- Automatic calibration for accurate results and easy operation

Reliable
- Can read strips with up to 14 parameters, including Microalbumin/Creatinine/Calcium
- Minimal training required

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

Easy Data Management
- Includes RS232C and USB ports for easy data transfer to an external computer or LIS
- Record Operator/Patient ID by Manual Entry and Barcode Reader

Specifications

Features	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	Single Test Option: 60 tests/hour Continuous Test Option: 120 tests/hour
Test Categories	Routine, STAT and QC
Memory	Last 2,000 results
Strip Incubation Time	1 Minute
Wavelength of Monochromatic LED	525 nm and 635 nm
Default Strips	8, 9, 10, 11 Parameters (108 mm x 5 mm)
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Total Combinations Per Analyzer	4 Combinations
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer USB Port for Data Transfer 25 Pin Parallel Port for External Printer
Data Entry Capabilities	Operator/Patient ID - Manual Entry and Barcode Reader (Up to 20 characters)
Connection Capabilities	Internal Thermal Printer (included) RS232C Barcode Reader (optional) Optional External Printer (not included) USB or RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), EAN 8, EAN 13, Interleave 25 , UPCA, UPCE
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤85% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	27.2 cm x 26.9 cm x 14.6 cm (10.7" x 10.6" x 5.7")
Display Dimensions (L x W)	10.8 cm x 5.7 cm (4.2" x 2.2")
Weight	2.6 kg (5.7 lbs) without batteries or power supply

Ordering Information

Product Name	Catalog No.	Components	Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U120 Urine Analyzer	U111-101√X	1 Urine Analyzer 1 Strip Holder 2 Printer Paper Rolls 2 Fuses (2.0A) 1 Power Cord 1 Quick Start Guide 1 Instruction Manual	42.0 cm x 41.5 cm x 31 cm; 5.0 kg 16.4" x 16.2" x 12.1"; 176.4 oz		1
U120 Urine Analyzer with Barcode Reader	U111-111√X	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls 1 Barcode Reader (RS232C) 2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Quick Start Guide 1 Instruction Manual	44.5cm x 44.5cm x 40.0cm; 5.5 kg 17.5" x 17.5" x 15.7"; 194 oz		1
Barcode Reader	U221-111√X	1 Barcode Reader (RS232C) 1 Serial Splitter Cable (RS232C)	23.6 cm x10.8 cm x 7.8 cm; 0.482 kg 9.3" x 4.3" x 3.1"; 17.0 oz	63.0 cm x 37.0 cm x 30.0 cm; 12.0 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls — Thermal Paper (0.06 m x 20 m): 200 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.36kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
		4 Printer Paper Rolls — Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
U120 Data Transfer Kit	U221-131√X	1 Data Transfer Cable (RS232C) 1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

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X **FDA 510(k) Cleared and CLIA Waived**

U120 Ultra Urine Analyzer

Easy to Operate
- Large color touchscreen LCD for simple menu navigation
- Work List and Help Menu available for specimen review and troubleshooting
- Powered by AC adaptor or 6 AA batteries for easy portability
- Up to 2,000 patient memory and 800 Operator ID storage
- Ability to select Time Logout between 1-99 with minutes or hours option

Accurate and Efficient
- Advanced CMOS Image Sensor ensures accurate readings
- Can read strips with up to 14 parameters, including Microalbumin, Creatinine and Calcium
- Option to edit test number sequence, or skip then return to specific test numbers
- Ability to edit abnormal results

Simple Data Transfer
- Immediate transmission of LIS data using Bluetooth, LAN or WLAN
- Ability to update software with SD card or USB flash drive

Unique Lockout Functions
- Strip Lockout
  - Pre-set option to prevent using strips of another brand, with a barcode reader or by manual entry
- User Lockout
  - Option to eliminate unapproved users with up to 800 operators
- QC Lockout
  - Prevents testing without passing QC
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

Specifications

Feature	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	CMOS Image Sensor
Throughput	Single Test Option: 55 tests/hour; Continuous Test Option: 120 tests/hour
Test Modes	Quick Test Mode, Full Test Mode and Customized Test Mode
Test Category	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 Records
Strip Incubation Time	1 Minute
Wavelength	390 nm - 770 nm
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations Per Analyzer	Over 15 Combinations
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer and External Printer USB Ports for Keyboard or Data Transfer
Data Entry Capabilities	Operator ID, Patient ID/Name - Manual Entry and Barcode Reader (Up to 20 characters) Urine Color and Clarity, Strip Lot Number, and Expiration Date - Manual Entry
Connection Capabilities	Internal Thermal Printer (included) Bluetooth (included) Bluetooth Adaptor (optional) RS232C Barcode Reader (optional) USB or RS232C Data Transfer Cable (optional) SD Card or USB flash drive for Software Update (optional) Ethernet via USB to RJ45 Adapter (optional) Keyboard (not included) Optional External Printer (not included)
Major Readable Barcodes	Code 39, Code 93, Code 128, Codabar (NW-7), EAN 8, EAN 13, EAN 128, French Pharmacode, Industrial 25, Interleave 25, Italy Pharmacode, Matrix 25, MSI, Plessey, RSS, Telepen, UPCA, UPCE
Screen Type	Large color touch screen LCD (12 cm x 9 cm)
LIS Interface	Formatted and compatible with HL-7 compliant, *ACON* standard interface, S interface, D interface, U interface and R interface for downloading of LIS data
Calibration	Automatic
Available Languages on the Screen	More than 10 languages available, including English
Analyzer Operating Conditions	0-40°C (32-104°F); 5%-85% RH
System Operating Conditions	15-30°C (59-86°F); 20%-80% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100- 240 VAC, 45-65 Hz; 6 AA Alkaline Batteries
Line Leakage Current	0.5 mA
Dimensions (L x W x H)	26 cm x 15 cm x 18 cm (10" x 6" x 7")
Display Dimensions (L x W)	12 cm x 9 cm (5" x 4")
Weight	1.7 kg (3.7 lb) without batteries or power supply

Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U120 Ultra Urine Analyzer	U114-101√	1 Urine Analyzer 2 Test Tables 2 Test Table Inserts 2 Printer Paper Rolls 1 Power Cord and Supply Adapter 1 Brush 1 Quick Start Guide 1 Instruction Manual		40 cm × 39 cm × 36 cm; 4 kg 16" x 15" x 14"; 141 oz		1
U120 Ultra Urine Analyzer with Barcode Reader	U114-111√	1 Urine Analyzer 2 Test Tables 2 Test Table Inserts 2 Printer Paper Rolls 1 Barcode Reader (RS232C) 1 Power Cord and Supply Adapter 1 Brush 1 Quick Start Guide 1 Instruction Manual		40 cm × 39 cm × 36 cm; 4 kg 16" x 15" x 14"; 141 oz		1
Barcode Reader	U124-111√	1 Barcode Reader (RS232C)		23.6 cm x10.8 cm x 7.8 cm; 0.36 kg 9.3" x 4.3" x 3.1"; 17.0 oz		22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.36 kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
			Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
U120 Ultra Data Transfer Kit	U124-131√	1 Data Transfer Cable (RS232C) 1 Package Insert		16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

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U500 Urine Analyzer

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

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

Convenient
- Automatic calibration and waste disposal reduce hands-on time
- Can read strips with up to 14 parameters, including Microalbumin/Creatinine/Calcium
- Strip selection of up to 4 combinations for analyzer reading
- Stores up to 2,000 records and automatically flags abnormal results
- Capable of printing results on sticker paper for quick and easy record management

Data Management Capability
- Includes RS232C port for easy data transfer to an external computer or LIS
- Record Operator/Patient ID by Manual Entry and Barcode Reader

Unique Lockout Functions
- Strip Lockout
  - Pre-set option to prevent using strips of another brand, with a barcode reader or by manual entry
- User Lockout
  - Option to eliminate unapproved users with up to 10 operators
- QC Lockout
  - Prevents testing without passing QC
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

Specifications

Feature	Specifications
Analyzer Type	Semi-Automatic
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	500 tests/hour (Measuring cycle: 7 seconds/test)
Test Categories	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 Records
Strip Incubation Time	1 Minute
Wavelength	525 and 635 nm
Default Strips	8, 9, 10, 11 Parameters (108 mm x 5 mm)
Strips Available	1-14 parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations Per Analyzer	4 Combinations
Waste Disposal Capacity	Up to 150 Strips
Analyzer Ports	RS232C Port for Barcode Reader or Data Transfer 25 Pin Parallel Port for External Printer
Data Entry Capabilities	Operator/Patient ID - Manual Entry and Barcode Reader (Up to 25 characters)
Connection Capabilities	Internal Thermal Printer (included) RS232C Barcode Reader (optional) Optional External Printer (not included) RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), EAN 8, EAN 13, Interleave 25, UPCA, UPCE
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤85% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	36.6 cm x 28.3 cm x 19.5cm (14.4" x 11.1" x 7.7")
Display Dimensions (L x W)	11.5 cm x 9.0 cm (4.5" x 3.5")
Weight	4.0 kg (8.8 lbs) without batteries or power supply

Ordering Information

Product Name	Catalog No.	Components		Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U500 Urine Analyzer	U211-101√†	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual	51.0 cm x 42.0 cm x 38.5 cm; 7 kg 20.1" X 16.5" x 15.2"; 246.9 oz		1
U500 Urine Analyzer with Barcode Reader	U211-111√†	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Instruction Manual	55.0 cm x 55.0 cm x 55.0cm; 9.2 kg 21.7" x 21.7" x 21.7"; 324.5 oz		1
Barcode Reader	U221-111√†	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x10.8 cm x 7.8 cm; 0. 482 kg 9.3" x 4.3" x 3.1"; 17.0 oz	63.0 cm x 37.0 cm x 30.0 cm; 12 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg 4.7" x 4.7" x 2.6"; 12.7oz	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz	50
			Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg 4.7" x 4.7" x 2.6"; 14.1oz	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	
U500 Data Transfer Kit	U221-131√†	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147kg 6.3" x 5.1" x 1.4"; 5.2 oz	25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

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Urine Controls

Reliable
- Use with *Mission*® and *Mission*® *Expert* Urinalysis Reagent Strips and Urine Analyzers for optimum quality control
- Validate urinalysis results and prevent procedure errors

Quick and Convenient Testing
- Ensures accurate results for all parameters
- Obtain quick results in any setting
- Competitively priced

Two Types of Urine Controls Available

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

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

Specifications

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

Ordering Information

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

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Mission® Urinalysis Reagent Strips (Urine)

Package Insert

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

For rapid detection of multiple analytes in human urine.
For in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

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

PRINCIPLE AND EXPECTED VALUES

Ascorbic acid: This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange. Patients with adequate diet may excrete 2-10 mg/dL daily. After ingesting large amounts of ascorbic acid, levels can be around 200 mg/dL.

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Glucose should not be detected in normal urine. Small amounts of glucose may be excreted by the kidney.[3] Glucose concentrations as low as 100 mg/dL may be considered abnormal if results are consistent.

Bilirubin: This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.[4-6] In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.[7]

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.035.[8] Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022.[8] In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue. Any green spots or green color development on the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females. The significance of a trace reading varies among patients and clinical judgment is required in these specimens.

pH: This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens from newborns is pH 5-7.[9] The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.[9]

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. 1-14 mg/dL of protein may be excreted by a normal kidney.[10] A color matching any block greater than trace indicates significant proteinuria. Clinical judgment is required to evaluate the significance of trace results.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen in strongly acidic medium to produce a pink color. Urobilinogen is one of the major compounds produced in heme synthesis and is a normal substance in urine. The expected range for normal urine with this test is 0.2-1.0 mg/dL (3.5-17 µmol/L).[8] A result of 2.0 mg/dL (35 µmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl) ethylenediamine to produce a pink color. Nitrite is not detectable in normal urine.[9] The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

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

REAGENTS AND PERFORMANCE CHARACTERISTICS

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

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

The performance characteristics of the Urinalysis Reagent Strips (Urine) have been determined in both laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed. Please refer to the Limitations section in this package insert.
Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the chart corresponds to a range of analyte concentrations.

PRECAUTIONS

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

STORAGE AND STABILITY

Store as packaged in the closed canister either at room temperature or refrigerated (2-30°C). Keep out of direct sunlight. The strip is stable through the expiration date printed on the canister label. Do not remove the desiccant. Remove only enough strips for immediate use. Replace cap immediately and tightly. **DO NOT FREEZE.** Do not use beyond the expiration date.
Note: Once the canister has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.
Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose.
Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

MATERIALS

Materials Provided

- Strips
- Package insert

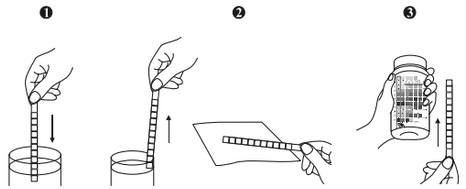
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

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



INTERPRETATION OF RESULTS

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

QUALITY CONTROL

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

LIMITATIONS

Note: The Urinalysis Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.[8] The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.
Ascorbic acid: No interference is known.
Glucose: The reagent area does not react with lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Sensitivity may be decreased in specimens with high specific gravity (>1.025) and with ascorbic acid concentrations of ≥ 25 mg/dL. High ketone levels ≥ 100 mg/dL may cause false negative results for specimens containing a small amount of glucose (50-100 mg/dL).
Bilirubin: Bilirubin is absent in normal urine, so any positive result, including a trace positive, indicates an underlying pathological condition and requires further investigation. Reactions may occur with urine containing large doses of chlorpromazine or rifampen that might be mistaken for positive bilirubin.[9] The presence of bilirubin-derived bile pigments may mask the bilirubin reaction. This phenomenon is characterized by color development on the test patch that does not correlate with the colors on the color chart. Large concentrations of ascorbic acid may decrease sensitivity.
Ketone: The test does not react with acetone or β-hydroxybutyrate.[8] Urine specimens of high pigment, and other substances containing sulfhydryl groups may occasionally give reactions up to and including trace (±).[9]
Specific Gravity: Ketoacidosis or protein higher than 300 mg/dL may cause elevated results. Results are not affected by non-ionic urine components such as glucose. If the urine has a pH of 7 or greater, add 0.005 to the specific gravity reading indicated on the color chart.
Blood: A uniform blue color indicates the presence of myoglobin, hemoglobin or hemolyzed erythrocytes.[8] Scattered or compacted blue spots indicate intact erythrocytes. To enhance accuracy, separate color scales are provided for hemoglobin and for erythrocytes. Positive results with this test are often seen with urine from menstruating females. It has been reported that urine of high pH reduces sensitivity, while moderate to high concentration of ascorbic acid may inhibit color formation. Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.
pH: If the procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing the pH result to appear artificially low. pH readings are not affected by variations in urinary buffer concentration.
Protein: Any green color indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein.[8] A negative result does not rule out the presence of these other proteins. False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results.[8] The urine specimens with high specific gravity may give false negative results.
Urobilinogen: All results lower than 1 mg/dL urobilinogen should be interpreted as normal. A negative result does not at any time preclude the absence of urobilinogen. The reagent area may react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamides.[9] False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.
Nitrite: The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red color should be interpreted as a positive result, suggesting the presence of nitrite. Color intensity is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Comparing the reacted reagent area on a white background may aid in the detection of low nitrite levels, which might otherwise be missed. Ascorbic acid above 30 mg/dL may cause false negatives in urine containing less than 0.05 mg/dL nitrite ions. The sensitivity of this test is reduced for urine specimens with highly buffered alkaline urine or with high specific gravity. A negative result does not at any time preclude the possibility of bacteruria. Negative results may occur in urinary tract infections from organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder for a sufficient length of time (at least 4 hours) for reduction of nitrate to nitrite to occur; when receiving antibiotic therapy or when dietary nitrate is absent.
Leukocytes: The result should be read between 60-120 seconds to allow for complete color development. The intensity of the color that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations (≥ 2,000 mg/dL) may cause test results to be artificially low. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein may diminish the intensity of the reaction color. This test will not react with erythrocytes or bacteria common in urine.[8]

BIBLIOGRAPHY

1. Free AH, Free HM. *Urinalysis, Critical Discipline of Clinical Science*. CRC Crit. Rev. Clin. Lab. Sci. 3(4): 481-531, 1972.
2. Yoder J, Adams EC, Free, AH. *Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH*. Amer. J. Med Tech. 31:285, 1965.
3. Shchersten B, Fritz H. *Subnormal Levels of Glucose in Urine*. JAMA 201:129-132, 1967.
4. McGarry JD, Lilly. Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, 1978.
5. Williamson DH. *Physiological Ketoses, or Why Ketone Bodies?* Postgrad. Med. J. (June Suppl.): 372-375, 1971.
6. Paterson P, et al. *Maternal and Fetal Ketone Concentrations in Plasma and Urine*. Lancet: 862-865; April 22, 1967.
7. Fraser J, et al. *Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk*. Clin. Chem. Acta II: 372-378, 1965.
8. Henry JB, et al. Clinical Diagnosis and Management by Laboratory Methods, 20th Ed. Philadelphia. Saunders. 371-372, 375, 379, 382, 385, 2001.
9. Tietz NW. Clinical Guide to Laboratory Tests. W.B. Saunders Company. 1976.
10. Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry 2nd Ed. 2205, 1994.

Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
EC REP	Authorized Representative				

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

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150310404
Effective date: 2011-03-14

STATEMENT

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

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

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

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092305 0001 Rev. 01

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

Certification Mark:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

Report No.: SH2198802

Valid from: 2022-04-11
Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

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

Facility(ies):

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

See Scope of Certificate

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ORGANIZED UNDER THE LAWS OF THE STATE OF TEXAS

NUMBER 9

PERCENT/UNITS

HEALGEN SCIENTIFIC LIMITED LIABILITY COMPANY

This Certifies that Zhejiang Orient Gene Biotech Co., Ltd. *is the owner of* one hundred (percent/unit(s)) *of the above Limited Liability Company transferable only on the books of the Company, subject to any restrictions set forth in State Law, the Formation Document or the Company Agreement, by the holder hereof in person or by duly authorized attorney upon surrender of this Certificate properly endorsed.*

In Witness Whereof, *the said Limited Liability Company has caused this Certificate to be signed by its duly authorized representative(s) and to be sealed with the Seal of the Company.*

Dated 6.31.2016

Nancy Ramsey
SECRETARY

PRESIDENT

HEALGEN SCIENTIFIC LIMITED LIABILITY COMPANY SEAL 2007 TEXAS

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

CE-DOC-OG038
Version 2.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

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

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

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

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

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

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

Date Signed: August 11, 2020

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

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

CE-DOC-OG106
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

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

Procalcitonin Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDPCT-402a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

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

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

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

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

Date Signed: August 7, 2018

Joyce Pang

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

3818 Fuqua street
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Tel: +1 713 733 8088
Fax: +1 713 733 8848
Web: www.Healgen.com
E-mail: sales@healgen.com

CE-DOC-H003
Ver.1.7

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: Healgen Scientific Limited Liability Company

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

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

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

EDMA Code: 15 70 02 02

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

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body
Notified Body: TÜV SÜD Product Service GmbH
Notified Body Address: Munich Branch Ridlerstraße 65 80339 München Germany
EC Certificate No.: V1 092378 0004 Rev. 02 Valid until: 2025-05-26
EC Design-Examination Certificate No.: V7 092378 0009 Rev. 00 Valid until: 2025-05-26

It bears the mark

CE 0123

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We hereby explicitly appoint
EC Representative Name: QARAD b.v.b.a.
EC Representative Address: Cipalstraat 3, B-2440 Geel, Belgium

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

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

Signature:
Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President
Date: 2022.4.22

Toxicology Urine Test

Product Description	Format	Cut-off Value	Qualification
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
Amphetamine (AMP) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Barbiturates (BAR) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/200 ng/mL	CE 510(k)
Benzodiazepines (BZO) Test	Strip/Cassette/Dip Card/Cup	600/400/300/200/100 ng/mL	CE 510(k)
Buprenorphine (BUP) Test	Strip/Cassette/Dip Card/Cup	10/5 ng/mL	CE 510(k)
Caffeine (CAF) Test	Strip/Cassette/Dip Card/Cup	6000 ng/mL	/
Carisoprodol (SOMA) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	CE
Clonazepam (CLO) Test	Strip/Cassette/Dip Card/Cup	500/100 ng/mL	CE
Cocaine (COC) Test	Strip/Cassette/Dip Card/Cup	600/300/150/100 ng/mL	CE 510(k)
Codeine (COD) Test	Strip/Cassette/Dip Card/Cup	2000 ng/mL	CE
Cotinine (COT) Test	Strip/Cassette/Dip Card/Cup	400/300/200/100/50 ng/mL	CE
Ecstasy (MDMA) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250/150 ng/mL	CE 510(k)
Ethyl Glucuronide (EtG) Test	Strip/Cassette/Dip Card/Cup	500/300ng/mL	CE
Fentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	300/200/100/50 ng/mL	CE
Norfentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCO) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
Ketamine (KET) Test	Strip/Cassette/Dip Card/Cup	3000/2000/1000/500/100 ng/mL	CE
Kratom (KRA) Test	Strip/Cassette/Dip Card/Cup	250/150/100 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Strip/Cassette/Dip Card/Cup	20 ng/mL	CE
Marijuana (THC) Test	Strip/Cassette/Dip Card/Cup	600/300/200/150/100/50/40/25/20/18/15 ng/mL	CE 510(k)
Methadone Metabolite (EDDP) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Methadone (MTD) Test	Strip/Cassette/Dip Card/Cup	1000/600/300/200/50 ng/mL	CE 510(k)
Methamphetamine (MET) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Methaqualone (MQL) Test	Strip/Cassette/Dip Card/Cup	300/1000 ng/mL	CE
Methcathinone (MTC) Test	Strip/Cassette/Dip Card/Cup	500/300 ng/mL	CE
3,4-Methylenedioxypyrovalerone (MDPV) Test	Strip/Cassette/Dip Card/Cup	1000/500/300 ng/mL	CE
Methylphenidate (MPD) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
6-Monoacetylmorphine (6-MAM) Test	Strip/Cassette/Dip Card/Cup	20/10 ng/mL	CE
Morphine (MOP) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/150/100 ng/mL	CE 510(k)
Opiate (OPI) Test	Strip/Cassette/Dip Card/Cup	2000/300/100 ng/mL	CE 510(k)
Oxycodone (OXY) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Phencyclidine (PCP) Test	Strip/Cassette/Dip Card/Cup	50/25 ng/mL	CE 510(k)
Pinaca Ab (K3) Test	Strip/Cassette/Dip Card/Cup	10 ng/mL	CE
Pregabalin (PGB) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500 ng/mL	CE
Propoxyphene (PPX) Test	Strip/Cassette/Dip Card/Cup	600/300 ng/mL	CE 510(k)
Synthetic Marijuana (K2) Test	Strip/Cassette/Dip Card/Cup	75/50/25/20/10 ng/mL	CE
Tramadol (TRA) Test	Strip/Cassette/Dip Card/Cup	200/100 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Strip/Cassette/Dip Card/Cup	1000/300 ng/mL	CE 510(k)
UR-144 Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	CE
Zolpidem (ZOL) Test New	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test New	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test

Product Description	Format	Cut-off Value	Qualification
7-Aminonclnozepam (ACL) Test New	Device	100 ng/mL	/
Amphetamine (AMP) Test	Device	50/40 ng/mL	CE
Barbiturates (BAR) Test	Device	300/50/40 ng/mL	CE
Benzodiazepines (BZO) Test	Device	50/20/10 ng/mL	CE
Buprenorphine (BUP) Test	Device	10/5 ng/mL	CE
Carisoprodol (SOMA) Test	Device	300 ng/mL	/
Cocaine (COC) Test	Device	50/20 ng/mL	CE
Codeine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Diphenhydramine (DIP) Test New	Device	150/100 ng/mL	/
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Ethyl Glucuronide (EtG) Test New	Device	150/100 ng/mL	/
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydrocodone (HCD) Test New	Device	10 ng/mL	/
Hydromorphone (HMO) Test New	Device	300/150 ng/mL	/
Ketamine (KET) Test	Device	100/50 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Device	25/10 ng/mL	CE
Marijuana (THC) Test	Device	50/40/30/25/15/12/10/5/4/3 ng/mL	CE
Methadone Metabolite (EDDP) Test	Device	20 ng/mL	CE
Mephedrone (MEP) Test New	Device	50 ng/mL	/
Methadone (MTD) Test	Device	75/50/30 ng/mL	CE
Methamphetamine (MET) Test	Device	50 ng/mL	CE
Methaqualone (MQL) Test	Device	150/100 ng/mL	CE
Methcathinone (MTC) Test	Device	50 ng/mL	/
3,4-Methylenedioxypyrovalerone (MDPV) Test	Device	200/100/50 ng/mL	CE
Methylphenidate (MPD) Test	Device	50 ng/mL	/
6-Monoacetylmorphine (6-MAM) Test	Device	25/15/10/5/4 ng/mL	CE
Morphine (MOP) Test	Device	15 ng/mL	CE
Opiate (OPI) Test	Device	50/40 ng/mL	CE
Oxycodone (OXY) Test	Device	50/40/20 ng/mL	CE
Phencyclidine (PCP) Test	Device	10 ng/mL	CE
Phenytoin (PHEN) Test New	Device	150/100 ng/mL	/
Pinaca Ab (K3) Test New	Device	10 ng/mL	/
Pregabalin (PGB) Test New	Device	100 ng/mL	/
Propoxyphene (PPX) Test	Device	50/20 ng/mL	CE
Synthetic Marijuana (K2) Test	Device	25/10/5 ng/mL	CE
Tramadol (TRA) Test	Device	100/50 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Device	1000/500/300/200 ng/mL	CE
XLR-11 Test New	Device	100 ng/mL	/
Zolpidem (ZOL) Test New	Device	25 ng/mL	/
Zopiclone (ZOP) Test New	Device	25 ng/mL	/
Alcohol (ALC) Test	Device	0.05,0.02%	CE

Toxicology Hair Test

Product Description	Format	Label	Cut-off Value	Qualification
Amphetamine (AMP) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	Fluorescence	0.2 ng/mg	/
		Gold	1 ng/mg	/
Cocaine (COC) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2 ng/mg	CE
Ecstasy (MDMA) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5 ng/mg	/
2-Fluorodeschloroketamin (FKE) Test	Cassette	Fluorescence	0.2 ng/mg	/
Ketamine (KET) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2/1.0/.5 ng/mg	CE
Marijuana (THC) Test	Cassette	Fluorescence	0.05 ng/mg	CE
		Gold	2/1.5 ng/mg	CE
Methamphetamine (MET) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	Fluorescence	0.2 ng/mg	CE
6-Monoacetylmorphine (6-MAM) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2 ng/mg	CE
Morphine (MOP) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5/2/0.5 ng/mg	CE
Oxycodone (OXY) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	4 ng/mg	/
Phencyclidine (PCP) Test	Cassette	Fluorescence	0.3 ng/mg	CE
		Gold	1 ng/mg	CE
Pinaca Ab (K3) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	0.5 ng/mg	/
Synthetic Marijuana (K2) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	1 ng/mg	/
Tramadol (TRA) Test	Cassette	Fluorescence	0.2 ng/mg	/
UR-144 Test	Cassette	Fluorescence	0.05 ng/mg	/

Infectious Disease

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Adenovirus Antigen Test	Swab	GCADE-502a/	Cassette	/	20 Tests/Kit
Adenovirus Test	Feces	GCADE-602a/	Cassette	/	20 Tests/Kit
Brucella Antibody Test	WB/S/P	GCBRU-402a/	Cassette	/	25 Tests/Kit
Candida albicans Test	Vaginal Secretion	GCCA-502a/	Cassette	10⁵ CFU/mL	20 Tests/Kit
Chagas Antibody Test	S/P	GCCHA-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHA-402a/	Cassette	/	25 Tests/Kit
Clostridium difficile GDH Test	Feces	GCCD(GDH)-602a/	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCCD(Toxin A/B)-602a/	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Clostridium difficile GDH & Toxin A/B Combo Test	Feces	GCCD-625a/	Cassette	GDH: 2 ng/mL Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Chikungunya IgM Test	S/P	GCCHK(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHK(IgM)-402a/	Cassette	/	25 Tests/Kit
Chikungunya IgG/IgM Test	WB/S/P	GCCHK(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
Chlamydia Test	Swab/Urine	GCCHL-502a/	Cassette	4.8×10⁵ IFU/mL	20 Tests/Kit
CMV IgG Test	S/P	GCCMV(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG)-402a	Cassette	/	25 Tests/Kit
CMV IgM Test	S/P	GCCMV(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgM)-402a	Cassette	/	25 Tests/Kit
CMV IgG/IgM Test	S/P	GCCMV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
COVID-19 IgM/IgG Test	WB/S/P	GCCOV-402a/	Cassette	/	25 Tests/Kit
COVID-19 Neutralizing Antibody Test	WB/S/P	GCCOV(NAb)-402b/	Cassette	/	25 Tests/Kit
COVID-19 Antigen Test	Nasopharyngeal Swab	GCCOV-502a/	Cassette	/	20 Tests/Kit
		GCCOV-502Ca/	Cassette	/	20 Tests/Kit
		GCCOV-501a/ New	Strip	/	20 Tests/Kit
	Nasal Swab	GCCOV-502a-NA/	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
		GCCOV-503a/ New	Device	/	1/2/5/10 Tests/Kit
	NA & NP Swab	GCCOV-502a-NN/	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-702a/	Cassette	/	20 Tests/Kit
COVID-19 Antigen Self-Test	Nasal Swab	GCCOV-502a-Hxx/	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
		GCCOV-502a-HxxOGE/	Cassette	/	1/2/3/5/7/8/10/15/20/25 Tests/Kit
	Oral Fluid	GCCOV-702a-Hxx/ New	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D503a/ New	Reader	/	1/2/3/5/7/10/15/20 Tests/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCCOV(B1117)-525a/	Cassette	/	20 Tests/Kit
COVID-19/Flu A&B /RSV Antigen Combo Test	Nasal Swab	GCFCR-T525a/ New	Cassette	/	20 Tests/Kit
SARS-CoV-2 Delta-series Mutant Strain Antigen Test	Nasal Swab	GCCOV(Del)-T502a/	Cassette	/	20 Tests/Kit
SARS-CoV-2 Ag Fluorescence Rapid Test	Nasal Swab	FCCOV-502a/ New	Cassette	/	20 Tests/Kit
Dengue IgG/IgM Antibody Test	WB/S/P	GCDEN(abi)-402c/	Cassette	/	25 Tests/Kit
Dengue NS 1 Antigen Test	WB/S/P	GCDEN(NS)-402c/	Cassette	/	25 Tests/Kit
Dengue NS1 & IgG/IgM Combo Test	WB/S/P	GCDEN-425a/	Cassette	/	20 Tests/Kit
EV71 IgM Test	S/P	GCEV71(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCEV71(IgM)-402a/	Cassette	/	25 Tests/Kit
Giardia lamblia Test	Feces	GCGIA-602a/	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b	Cassette	1.0E+7	20 Tests/Kit
HAV IgM Test	S/P	GCHAV(IgM)-302Ba/	Cassette	/	25 Tests/Kit
HAV IgG/IgM Test	WB/S/P	GCHAV(IgG/IgM)-402a/	Cassette	/	25 Tests/Kit
HAV AntigenTest	Feces	GCHAV-602a/	Cassette	/	25 Tests/Kit
HBcAb Hepatitis B Core Antibody Test	S/P	GCHBcb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBcb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBcb-402a	Cassette	2 NCU	25 Tests/Kit
HBeAb Hepatitis B Envelope Antibody Test	S/P	GCHBeb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBeb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBeb-402a	Cassette	2 NCU	25 Tests/Kit
HBeAg Hepatitis B Envelope Antigen Test	S/P	GCHBeg-302a	Cassette	0.5 NCU	25 Tests/Kit
	WB/S/P	GCHBeg-402a	Cassette	0.5 NCU	25 Tests/Kit
HBsAb Hepatitis B Surface Antibody Test	S/P	GCHBsb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCHBsb-302a	Cassette	30 mIU/mL	25 Tests/Kit
		GCHBsb-401a	Strip	30 mIU/mL	50 Tests/Kit
	WB/S/P	GCHBsb-402a	Cassette	20 mIU/mL	25 Tests/Kit
		GCHBsb-402b	Cassette	20 mIU/mL	25 Tests/Kit
HBsAg Hepatitis B Surface Antigen Rapid Test	S/P	GCHBsg-301a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-302a	Cassette	1 ng/mL	25 Tests/Kit
	WB/S/P	GCHBsg-401a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-402a	Cassette	1 ng/mL	25 Tests/Kit
HBsAg/HCV Combo Test	WB/S/P	GCHBC-402a	Cassette	/	25 Tests/Kit
HBsAg/HCV/HIV/Syphilis Combo Test	S/P	GCHBCISY-345a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBCISY-445a	Cassette	/	20 Tests/Kit
HBV HBcAb/HBeAb/HBeAg/HBsAb /HBsAg Combo Test	S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBV-455a	Cassette	/	20 Tests/Kit
HCV Hepatitis C Virus Test	S/P	GCHCV-301a	Strip	/	50 Tests/Kit
		GCHCV-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHCV-401a	Strip	/	50 Tests/Kit
		GCHCV-402a/	Cassette	/	25 Tests/Kit
HCV/HIV Combo Test	WB/S/P	GCHCI-402a	Cassette	/	25 Tests/Kit
HEV Hepatitis E Virus IgM Test	S/P	GCHEV-302a/	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Test	S/P	GCHIV-301a	Strip	/	50 Tests/Kit
		GCHIV-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHIV-401a	Strip	/	50 Tests/Kit
		GCHIV-402a/	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Tri-line Test	WB/S/P	GCHIV-GT402a	Cassette	/	25 Tests/Kit
HIV 1/2/O Antibody Test	S/P	GCHIV-T302b	Cassette	/	25 Tests/Kit
	WB/S/P	GCHIV-T402a	Cassette	/	25 Tests/Kit
HIV Antigen/Antibody Combo Test	WB/S/P	GCHIV(Ag/Ab)-402a	Cassette	/	25 Tests/Kit
HSV IgG Test	S/P	GCHSV(IgG)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG)-402a/	Cassette	/	25 Tests/Kit
HSV IgM Test	S/P	GCHSV(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgM)-402a/	Cassette	/	25 Tests/Kit
HSV IgG/IgM Test	S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
H. pylori Antibody Test	S/P	GCHP-301a/	Strip	/	50 Tests/Kit
		GCHP-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHP-401a/	Strip	/	50 Tests/Kit
		GCHP-402a/	Cassette	/	25 Tests/Kit
H. pylori Antigen Test	Feces	GCHP-601a/	Strip	/	25 Tests/Kit
		GCHP-601Ca/	Strip	/	25 Tests/Kit
		GCHP-602a/	Cassette	/	20 Tests/Kit
		GCHP-602Ca/	Cassette	/	20 Tests/Kit
Influenza A Antigen Test	Nasal/Throat Swabs	GCFLU(A)-501a/	Strip	1.5 x 10⁵ TCID$_{50}$	25 Tests/Kit
		GCFLU(A)-502a/	Cassette	1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
Influenza A/B Antigen Test	Nasal/Throat Swabs	GCFLU(A/B)-501a/	Strip	1.5x 10⁵ TCID$_{50}$/ 1.5 x 10⁵ TCID$_{50}$	25 Tests/Kit
		GCFLU(A/B)-502a/	Cassette	1.5x 10⁵ TCID$_{50}$/ 1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
		GCFLU(A/B)-502Ca/	Cassette	1.5x 10⁵ TCID$_{50}$/ 1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
Influenza & COVID-19 Antigen Combo Test	Nasopharyngeal Swab	GCFC-525a/	Cassette	/	20 Tests/Kit
	NA & NP Swab	GCFC-525a-NN/	Cassette	/	20 Tests/Kit
		GCFC-525a-NA/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFC-T502a/ New	Cassette	/	1/5/20 Tests/Kit
		GCFC-T503a/ New	Device	/	1/2/5/10 Tests/Kit
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFCRA-545a/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFCRA-T525a/ New	Cassette	/	20 Tests/Kit
Leishmania Antibody Test	S/P	GCKal-301a	Strip	/	50 Tests/Kit
		GCKal-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCKal-401a/	Strip	/	50 Tests/Kit
		GCKal-402a	Cassette	/	25 Tests/Kit
Malaria Pan Antigen Test	Whole Blood	GCMAL(pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f. Antigen Test	Whole Blood	GCMAL(pf)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./Pan Antigen Test	Whole Blood	GCMAL(pf/pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antigen Test	Whole Blood	GCMAL(pf/pv)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antibody Test	S/P	GCMAL(pf/pv Ab)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCMAL(pf/pv Ab)-402a/	Cassette	/	25 Tests/Kit
Monkeypox IgG/IgM Antibody Test	WB/S/P	GCMKP-402a/ New	Cassette	/	25 Tests/Kit
Monkeypox Antigen Test	WB/S/P or Throat swab	GCMKP-502a/ New	Cassette	/	25 Tests/Kit
Mononucleosis Test	S/P	GCMON-325a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCMON-402a/	Cassette	/	25 Tests/Kit
		GCMON-425a/	Cassette	/	25 Tests/Kit
M. pneumonia IgM Test	S/P	GCMP(IgM)-302a/	Cassette	/	25 Tests/Kit
Respiratory Syncytial Virus Antigen Test	Swab	GCRSV-502a/	Cassette	/	20 Tests/Kit
Rotavirus Test	Feces	GCROA-602a/	Cassette	/	25 Tests/Kit
Rotavirus/Adenovirus Test		GCROA/ADE-602a/	Cassette	/	25 Tests/Kit
Rubella IgG Test	S/P	GCRUB(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG)-402a	Cassette	/	25 Tests/Kit
Rubella IgM Test	S/P	GCRUB(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgM)-402a	Cassette	/	25 Tests/Kit
Rubella IgG/IgM Test	S/P	GCRUB(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
		GCRUB(IgG/IgM)-T402a	Cassette	/	25 Tests/Kit
Strep A Test	Throat Swab	GCSTR-501a/	Strip	/	25 Tests/Kit
		GCSTR-501Ca/†	Strip	/	25 Tests/Kit
		GCSTR-502a/	Cassette	/	20 Tests/Kit
		GCSTR-502Ca/	Cassette	/	20 Tests/Kit
Syphilis Test	S/P	GCSYP-301a/	Strip	/	50 Tests/Kit
		GCSYP-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCSYP-401a/	Strip	/	50 Tests/Kit
		GCSYP-402a/	Cassette	/	25 Tests/Kit
S. typhi Antigen Test	S/P/Feces	GCSAL(ST)-602a/	Cassette	/	20 Tests/Kit
TOXO IgG Test	S/P	GCTOXO(IgG)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOXO(IgG)-402a	Cassette	/	25 Tests/Kit
TOXO IgM Test	S/P	GCTOXO(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOXO(IgM)-402a	Cassette	/	25 Tests/Kit
Toxo IgG/IgM Test	S/P	GCTOX-302b	Cassette	/	25 Tests/Kit
		GCTOX(IgG/IgM)-302a/	Cassette	/	20 Tests/Kit
	WB/S/P	GCTOX-402b	Cassette	/	25 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgG Combo Test	S/P	GCTOG-345a	Cassette	/	20 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgM Combo Test	S/P	GCTOM-345a	Cassette	/	20 Tests/Kit
Trichomonas vaginalis Test	Vaginal Swab	GCTV-502a/	Cassette	/	20 Tests/Kit
Tuberculosis IgG/IgM Test	S/P	GCTB-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTB-402a/	Cassette	/	25 Tests/Kit
Typhoid IgG/IgM Test	S/P	GCTYP-301a	Strip	/	50 Tests/Kit
		GCTYP-302a/	Cassette	/	25 Tests/Kit
V. cholerae O1 Antigen Test	Feces	GCVCHO(O1)-602a/	Cassette	/	25 Tests/Kit
V. cholerae O1/O139 Antigen Test	Feces	GCVCHO(O1/O0)-602a/	Cassette	/	25 Tests/Kit
ZIKA IgM Test	WB/S/P	GCZIK(IgM)-402a	Cassette	/	25 Tests/Kit
ZIKA IgG Test	WB/S/P	GCZIK(IgG)-402a	Cassette	/	25 Tests/Kit
ZIKA NS1 Test	WB/S/P	GCZIK(NS1)-402a	Cassette	/	25 Tests/Kit

√CE Marked †Cleared for US 510(k) In Specimen column: WB: Whole Blood S: Serum P: Plasma

Fertility


Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
hCG Pregnancy Test	Urine	GAHCG-101a/†	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-101b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-101d/	Strip	20 mIU/mL	100 Tests/Kit
		GAHCG-102a/†	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-102b/	Cassette	10 mIU/mL	25 Tests/Kit
		GAHCG-102d/	Cassette	20 mIU/mL	25 Tests/Kit
		GAHCG-103a/†	Midstream	25 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103b/	Midstream	10 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103d/	Midstream	20 mIU/mL	1/2 Test(s)/Kit
		GAHCG-105a	Panel	25 mIU/mL	25 Tests/Kit
	Urine/Serum	GAHCG-201a/	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-201b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-202a/	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-202b/	Cassette	10 mIU/mL	25 Tests/Kit
Digital Pregnancy Test	Urine	GAHCG-D103a/	Midstream	25 mIU/mL	1/2 Test(s)/Kit
LH Ovulation Test	Urine	GALH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GALH-101b/	Strip	40 mIU/mL	100 Tests/Kit
		GALH-101d	Strip	30 mIU/mL	100 Tests/Kit
		GALH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
		GALH-102b/	Cassette	40 mIU/mL	25 Tests/Kit
		GALH-103a/	Midstream	25 mIU/mL	1/5 Test(s)/Kit
		GALH-103b/	Midstream	40 mIU/mL	1/5 Test(s)/Kit
		GALH-103d	Midstream	30 mIU/mL	1/5 Test(s)/Kit
FSH Menopause Test	Urine	GAFSH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GAFSH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
IGFBP-1 PROM Test	Cervical Secretion	GAIGF1-501a/	Strip	25 ng/mL	25 Tests/Kit
		GAIGF1-502a/	Cassette	25 ng/mL	20 Tests/Kit
Male Fertility Test	Semen	GASPE-902a/	Cassette	15M/mL	1 Test/Kit

Cardiac Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
CK-MB Test	S/P	GDCKM-302a/	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GDCKM-402a/	Cassette	5 ng/mL	25 Tests/Kit
CRP C-Reactive Protein Semi -Quantitative Test	WB/S/P	GDCRP-402a/	Cassette	1–3–10 mg/L	25 Tests/Kit
		GDCRP-T402b/	Cassette	10–40–80 mg/L	25 Tests/Kit
D-dimer Test	WB/P	GDDDI-402b/	Cassette	500 ng/mL	25 Tests/Kit
Myoglobin Test	WB/S/P	GDMYO-402a/	Cassette	50 ng/mL	25 Tests/Kit
Procalcitonin Test	WB/S/P	GDPCT-T402a/	Cassette	0.5–2–10 ng/mL	25 Tests/Kit
Troponin I Test	S/P	GDTRO-302a/	Cassette	0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDTRO-402a/	Cassette	0.5 ng/mL	25 Tests/Kit
		GDTRO-402b/	Cassette	0.5 ng/mL	25 Tests/Kit
Cardiac Myoglobin/CK - MB/cTnI Combo Test	S/P	GDCAR-335a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDCAR-435a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
		GDCAR-W435a/	Cassette	50/5/0.5 ng/mL	20 Tests/Kit

Urinalysis


Product Description	Specimen	Format	Cut-off Value	Kit Size
Ascorbate√†	Urine	Strip	0.5-0.6 mmol/L	100 Tests/Canister
Bilirubin√†	Urine	Strip	8.6-17 μmol/L	100 Tests/Canister
Blood√†	Urine	Strip	5-15 Ery/μL	100 Tests/Canister
Ca√	Urine	Strip	2.5 mmol/L	100 Tests/Canister
Creatinine√	Urine	Strip	50 mg/dL	100 Tests/Canister
Glucose√†	Urine	Strip	2.8–5.5 mmol/L	100 Tests/Canister
Ketone√†	Urine	Strip	0.5–1.0 mmol/L	100 Tests/Canister
Leukocytes√†	Urine	Strip	5-15 Leuko/μL	100 Tests/Canister
Micro Albumin√	Urine	Strip	0.08–0.15 mg/dL	100 Tests/Canister
Nitrite√†	Urine	Strip	13–22 μmol/L	100 Tests/Canister
pH√†	Urine	Strip	0.5	100 Tests/Canister
Protein√†	Urine	Strip	0.15–0.3 g/L	100 Tests/Canister
Specific Gravity√†	Urine	Strip	0.005	100 Tests/Canister
Urobilinogen√†	Urine	Strip	3.3-16 μmol/L	100 Tests/Canister
Urinary Tract Infection Test Strip	Urine	Strip	LEU: 10-15 Leuko/μL NIT: 13–22 μmol/L	3 Tests/Kit

Tumor Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
AFP Alpha Fetal Protein Test	S/P	GEAFP-301a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-302a/	Cassette	20 ng/mL	25 Tests/Kit
	WB/S/P	GEAFP-401a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-402a/	Cassette	20 ng/mL	25 Tests/Kit
CEA Carcinoembryonic Antigen Test	S/P	GECEA-301a	Strip	5 ng/mL	50 Tests/Kit
		GECEA-302a	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GECEA-401a/	Strip	5 ng/mL	50 Tests/Kit
		GECEA-402a/	Cassette	5 ng/mL	25 Tests/Kit
FOB Fecal Occult Blood Test	Feces	GEFOB-601b/†	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601Cb/	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601c/	Strip	100 ng/mL	25 Tests/Kit
		GEFOB-601d	Strip	200 ng/mL	25 Tests/Kit
		GEFOB-602b/†	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602Cb/	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602c/	Cassette	100 ng/mL	20 Tests/Kit
		GEFOB-602d	Cassette	200 ng/mL	20 Tests/Kit
		GEFOB-602h	Cassette	150 ng/mL	20 Tests/Kit
		GEFOB-602j/	Cassette	10 ng/mL	20 Tests/Kit
FOB /Transferrin Combo Test	Feces	GEFOB/TF-602a/	Cassette	50/10 ng/mL	20 Tests/Kit
Nuclear Matrix Protein 22 Test	Urine	GENMP22-102a/ New	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate Specific Antigen Test	S/P	GEPSA-301a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-302a/	Cassette	4 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-401a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a/	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-QuantitativeTest	S/P	GEPSA-302b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-402b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
Transferrin Test	Feces	GETF-601a/	Strip	10 ng/mL	25 Tests/Kit
		GETF-602a/	Cassette	10 ng/mL	20 Tests/Kit

Veterinary

Product Description	Specimen	Catalog No.	Format	Label	Cut-off Value	Kit Size
Canine Adenovirus (CAV) Antigen Test	Secretions	GFCAV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Coronavirus (CCV) Antigen Test	Feces	GFCCV-602a	Cassette	Gold	/	10 Tests/Kit
		FFCCV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Coronavirus (CCV) & Parvovirus (CPV) Antigen Combo Test	Feces	GFCCP-T602a	Cassette	Gold	/	10 Tests/Kit
		FFCCP-T602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine C-Reactive Protein (cCRP) Test	WB/S/P	FFCCR-402a	Cassette	Fluorescence	10 mg/L	10 Tests/Kit
Canine Distemper Virus (CDV) Antigen Test	Secretions	GFCDV-502a	Cassette	Gold	/	10 Tests/Kit
		FFCDV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Distemper Virus (CDV), Influenza Virus (CIV) & Adenovirus (CAV) Antigen Combo Test	Secretions	GFCDIA-532a	Cassette	Gold	/	10 Tests/Kit
Canine Influenza Virus (CIV) Antigen Test	Secretions	GFCIV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	Feces	GFCPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFCPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Progesterone (cProg) Test	WB/S/P	FFCPR-402a	Cassette	Fluorescence	15 ng/mL	10 Tests/Kit
Feline Calicivirus (FCV) Antigen Test	Secretions	GFFCV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFCV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Coronavirus (FCoV) Antigen Test	Feces	GFFCO-602a	Cassette	Gold	/	10 Tests/Kit
Feline Herpes Virus (FHV) Antigen Test	Secretions	GFFHV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFHV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) Antigen Test	Feces	GFFPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFFPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test	Feces	GFFPC-622a	Cassette	Gold	/	10 Tests/Kit
Feline Serum Amyloid A (fSAA) Test	WB/S/P	FFFSA-402a	Cassette	Fluorescence	5 mg/L	10 Tests/Kit
Toxoplasma (Toxo) IgG/IgM Test	WB/S/P	GFTOX-402a	Cassette	Gold	/	10 Tests/Kit

Non-Infectious Disease

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Micro-Albumin Test	Urine	GIHSA-101a/	Strip	20 μg/mL	100 Tests/Kit
		GIHSA-102a	Cassette	20 μg/mL	25 Tests/Kit
Vaginal pH Test	Vaginal Secretion	VPH-501a New	Strip	3.8-4.4	100 Tests/Canister

Autoimmunity

Product Description	Specimen	Catalog No.	Format	Kit Size
Rheumatoid Factor IgM Test	S/P	GCRFIgM-302a	Cassette	25 Tests/Kit
Total IgE Test	S/P	GCIGE-302a	Cassette	25 Tests/Kit

Instrument



Product Description	Model
Urine Analyzer	Healgen 500√
Urine Analyzer	Healgen 501√
Colloidal Gold Test Reader	OG-D180
Handheld Oral Fluid Drug Test Reader	OG-D200
Multi-Function Colloidal Gold Test Reader	OG-D600
Fluorescence Immunoassay Analyzer	OG-G200
Handheld Fluorescence Immunoassay Analyzer	OG-G300
Mini Immunofluorescence Analyzer	OG-H100√
Veterinary Fluorescence Immunoassay Analyzer	OG-V100

√CE Marked †Cleared for US 510(k) In Specimen column: WB: Whole Blood S: Serum P: Plasma

HEALGEN®

Zhejiang Orient Gene Biotech Co., Ltd was founded in December 2005 and listed on the SEE STAR Market on February 5, 2020 (securities code: 688298).
Orient Gene specializes in R&D, production and sales of in vitro diagnostic products, mainly covering infectious diseases (including COVID-19 test series), toxicology, tumor markers, cardiac markers and fertility testing, etc. Through 16 years of technology accumulation and continuous investment in R&D, the Company has independently developed hundreds of products. The company own more than 200 authorized patents, and has obtained more than 500 product medical device certifications at home and abroad. The Company's sales network covers more than 100 countries, products are mainly sold to Europe, America and other developed countries.

Healgen Scientific LLC, a wholly owned subsidiary of Zhejiang Orient Gene Biotech Co., Ltd develops, manufactures and commercializes in vitro diagnostic test systems worldwide. Our product portfolio spans multiple testing categories and analytes to meet various clinical and laboratory needs.

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PRODUCT CATALOG

Enhancing Global Health

HEALGEN®

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

INTENDED USE

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

INTRODUCTION

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

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

PRINCIPLE

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

PRODUCT CONTENTS

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

MATERIALS SUPPLIED

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

MATERIAL REQUIRED BUT NOT PROVIDED

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

STORAGE AND STABILITY

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

WARNINGS AND PRECAUTIONS

1.For professional In Vitro diagnostic use only. Do not use after expiration date.
2.Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4.Test is for single use only. Do not re-use under any circumstances.
5.Handle all specimens as if they contain infectious agents.Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results .

SPECIMEN COLLECTION

1.The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2.To collect Fingerstick Whole Blood specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
  · Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
  · Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
- Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:
  · Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
  · Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device or, move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

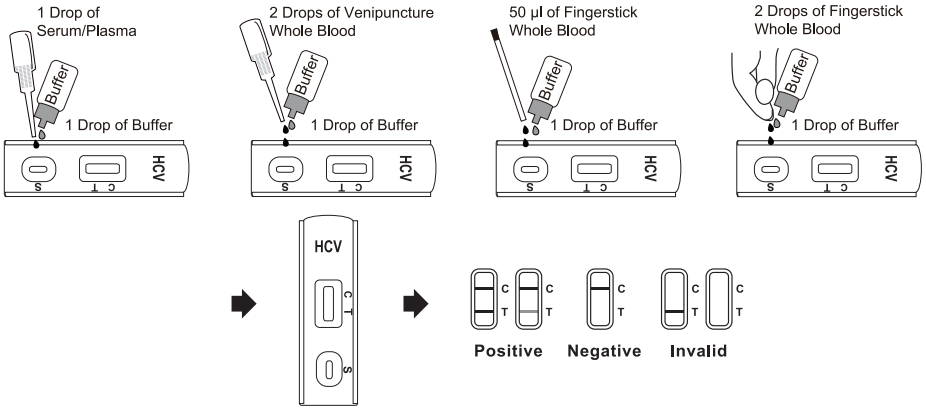
3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4.Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5.Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6.If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

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

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



INTERPRETATION OF RESULTS

(please refer to the illustration above)

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

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

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

QUALITY CONTROL

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

LIMITATIONS

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

PERFORMANCE CHARACTERISTICS

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

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

The HCV Ab Rapid Test Cassette vs EIA test

Method		EIA		Total Results
HCV Ab RapidTest	Results	Positive	Negative	
	Positive	105	19	124
	Negative	2	1760	1762
Total Results		107	1779	1886

Relative sensitivity: 98.1%
Relative specificity: 98.9%
Accuracy: 98.9%

REFERRENCE

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

Troponin I

Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.[1] Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.[2] After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.[3] cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.[4] Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.[5]

PRINCIPLE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region.
During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.
Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

1. For professional In Vitro diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re- use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
7. Humidity and temperature can adversely affect results

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Disposable Droppers
- Package insert

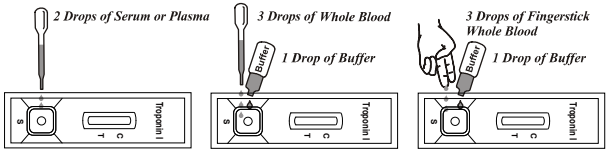
Materials Required But Not Provided

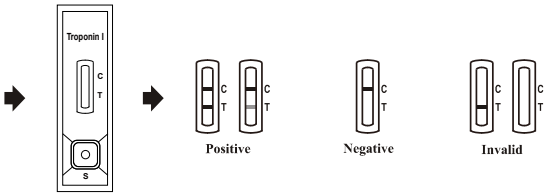
- Specimen collection containers
- Centrifuge (for plasma only)
- Clock or Timer

DIRECTIONS FOR USE

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

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. Transfer 2 drops of serum or plasma to the specimen well of the device with a disposable pipette provided in the kit, and then start the timer.
   OR
   Transfer 3 drops of whole blood specimen to the specimen well of the device with a disposable pipette provided in the kit, then add 1 drop of buffer, and start the timer.
   OR
   Allow 3 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer, and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.
   As the test begins to work, you will see color move across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE:Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
NEGATIVE:Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).
INVALID:Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.
Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

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

LIMITATIONS

1. The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
2. The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

Method		Troponin I Rapid Test Device		Total Results
EIA	Results	Positive	Negative	
	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

Relative Sensitivity: 98.6% (94.9%-99.8%)*
Relative Specificity: 99.7% (98.3%-99.9%)*
Overall Agreement: 99.3% (98.1%-99.9%)*
*95% Confidence Interval

BIBLIOGRAPHY

1. Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
3. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
4. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.

Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

A rapid test for the Semi-Quantitative detection of Procalcitonin in whole blood, serum or plasma specimens.

For professional *in vitro* diagnostic use only.

INTENDED USE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is used for semi-quantitative determination and monitoring of PCT concentrations in whole blood/serum/plasma specimens.

SUMMARY

The Procalcitonin (PCT) is a peptide hormone mainly produced by the C cells of the thyroid and certain endocrine cells of the lung. Under normal expression conditions, procalcitonin is immediately cleaved into three specific fragments, an N terminal residue, calcitonin and katacalcin, Levels of unprocessed procalcitonin rise significantly after bacterial infection, trauma or shock.

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that semi-qualitatively detects the presence of Procalcitonin in whole blood, plasma or serum specimens at the sensitivity of 0.5ng/mL, 2ng/mL and 10ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of Procalcitonin in whole blood, plasma or serum. At the level of claimed sensitivity, the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) shows no cross-reactivity interference from the structurally related CRP or others at high physiological levels.

PRINCIPLE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) detects Procalcitonin through visual interpretation of color development on the internal strip. Anti-PCT antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-PCT antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If Test band 3 (T3) appears, it indicates that the PCT level in the specimen is between 0.5-2.0ng/ml. If the Test band 3 and 2 (T3 and T2) appear, it indicates that the PCT level in the specimen is between 2.0-10.0 ng/ml. If all the Test bands (T1, T2, T3), it indicates that the PCT level is above 10.0 ng/ml. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains anti- Procalcitonin particles and anti- Procalcitonin coated on the membrane.

MATERIALS PROVIDED

25 Sealed pouches each containing a test cassette, a dropper and a desiccant

1 Buffer, 4.0 mL

1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container 2. Timer 3. Centrifuge

• PRECAUTIONS

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

STORAGE AND STABILITY

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

Do not freeze.

Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

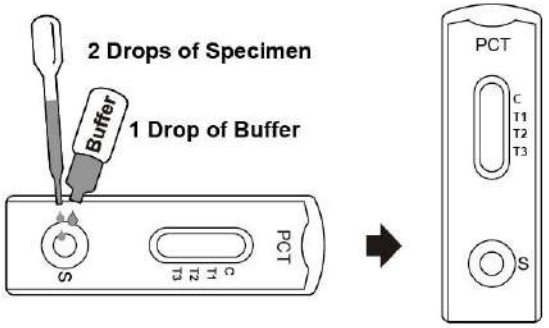
SPECIMEN COLLECTION AND PREPARATION

- The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Add **2 drops of specimen** above to the specimen well and then add **1 drop of buffer**, start the timer.
3. Wait for the colored bands to appear. The result should be **read at 10 minutes**. Do not interpret the result after 20 minutes.

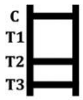


INTERPRETATION OF RESULTS

POSITIVE RESULT:

Possible Interpretation of Procalcitonin Levels

A Control band (C) and a test band (T3) appears indicates a PCT level 0.5 mg/L at least.



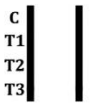
A Control band (C) and two test bands (T3 and T2) appear indicates a PCT level 2.0 mg/L at least.

A Control band (C) and three test bands (T1, T2 and T3) appears indicates a PCT level 10.0 mg/L at least.

NEGATIVE RESULT:

Only a Control band (C) appears and no colored band appears in the test region (T) indicates a PCT level is lower than 0.5 mg/L.

INVALID RESULT:



No Control band appears. Results from any test which has not produced Control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a semi-quantitative test only, and cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. Control band appearing in the control regions is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the semi-quantitative detection of Patent Cooperation Treaty.

2. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of PCT in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.

3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

4. PCT values near the cut-off level Test line 3 (T3: 0.5 ng/ml), Test line 2 (T2: 2.0 ng/ml), and Test line 1 (T1: 10.0 ng/ml) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than T1 can also represent a value slightly below 10.0 ng/ml. Similar observations may occur with values near 2.0 ng/ml and 0.5 ng/ml. A repeat test or further quantitative test is recommended in such cases.

EXPECTIED VALUES

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Procalcitonin EIA test, demonstrating an overall accuracy of 98.9%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial Procalcitonin EIA test using clinical specimens. The results show that the sensitivity of the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.8% and the specificity is 99.0% relative to the leading EIA test.

Procalcitonin Semi-Quantitative Rapid Test Cassette vs. EIA

Method		**EIA Test**		Total Results
Semi-Quantitative Rapid Test Cassette	Results	Positive	Negative	
	Positive	84	2	86
	Negative	1	193	194
Total Results		85	195	280

Relative Sensitivity: 98.8%(93.6%-99.9%)*

Relative Specificity: 99.0%(96.3%-99.9%)*

Accuracy: 98.9%(96.9%-99.8%)* *95% Confidence Interval

LITERATURE REFERENCES

1. Müller B. et al.: Calcitonin precursors are reliable markers of sepsis in medical intensive care unit. Crit. Care Med. 2000, 28(4): 977-983

2. Harbarth S. et al.: Diagnostic value of procalcitonin, inter- leukin-6 and interleukin 8 in critically ill patients admitted with suspected sepsis. Am. J. Resp. Crit. Care Med. 2001, 164: 396-402

3. Brunkhorst F.M. et al.: Procalcitonin for early diagnosis and differentiation of SIRS, sepsis, severe sepsis and septic shock. Intensive Care Med. 2000, 26(suppl.2): 148-152

4. Meisner M.: Procalcitonin (PCT) – A new, innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0

5. Meisner M. et al.: Procalcitonin – Influence of temperature, storage, anticoagulation and arterial or venous asservation of blood samples on procalcitonin concentrations. Eur J Clin Chem Clin Biochem 1997, 35 (8): 597-601

6. American College of Chest Physicians/Society of Critical Care Medicine: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. Crit Care Med 1992, 20: 864-874

7. Morgenthaler N. et al.: Detection of procalcitonin (PCT) in healthy controls and patients with local infection by a sensitive ILMA. Clin Lab. 2002. 48(5-6): 263-70

8. MeisnerM,etal.:Clinicalexperienceswithanew,semiquanti- tative solid phase immunoassay for rapid measurement of procalcitonin. Clin. Chem. Lab. Med. 2000, 38(10): 989-995

9. Chiesa C, Panero A, Rossi N, Stegagno M, De Giusti M, Osborn JF, Pacifico L. Clin Infect Dis (1998), 26: 664-672: Re- liability of Procalcitonin Concentrations for the Diagnosis of Sepsis in Critically Ill Neonates

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GDPCT-T402a

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