



/ **77 ELEKTRONIKA KFT.**
H-1116 Budapest, Fehérvári út 98.
/ Telefon +36 1 206 1480
/ Web: E77.HU

For submission at the competent

Authorities of Republic of Moldova

Letter of Authorization

Whereas, **77 Elektronika Kft** (based at Fehérvári út 98, 1116 – Budapest (Hungary) as manufacturer of Urilyzer® Cell (Urine Microscopy Analyzer) and Urilyzer® Cell Cuvettes (Cuvette for Urine Microscopy Analyzer) do hereby declare that

Sanmedico SRL, str. Petricani 88/1, 0259 Chisinau - Republic of Moldova

is authorized to register, import, promote sell and support the above-mentioned products under the trademark "Urilyzer®" non-exclusively within the territory of Republic of Moldova as a Distributor. We authorize **Sanmedico SRL** to overtake the procedures regarding the registration of the mentioned products at the Authorities of Republic of Moldova. **Sanmedico SRL** is authorized to participate in tenders only in the territory of Republic of Moldova.

Analyticon Biotechnologies GmbH (based at Am Muehlenberg 10, 35104 Lichtenfels (Germany) as distributor of 77 Elektronika Kft is the owner of the trademark "Urilyzer®". 77 Elektronika Kft confirms, that Analyticon Biotechnologies GmbH is the brand owner of the above-mentioned products.

This Letter of Authorization is valid until 31.12.2023. It could be elongated by 77 Elektronika Kft for another period in accordance with **Sanmedico SRL** Cancellation must be in writing with a cancellation period of 3 Months for each party.

For and on behalf of 77 Elektronika Kft

Signed on 17th July 2023, Budapest, Hungary

Sándor Zetwitz

managing director

77 Elektronika Műszeripari Kft.
H-1116 Budapest,
Fehérvári út 98.
23.



Management
Systems
ISO 9001
ISO 13485
ISO 14001
www.tuv.com

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

Scope: Design and development, production, distribution, installation and servicing of blood glucose measuring systems, urine analyzers and rapid test readers, including related consumables.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

A blue ink signature is written over a circular stamp. The stamp contains the TÜV Rheinland logo and the text "TÜV Rheinland LGA Products GmbH" and "Zertifizierungsstelle".

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design and development, production, distribution, installation and servicing.
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary	Manufacture and warehouse of blood glucose measuring systems, urine analyzers, related consumables and parts. Manufacturing of SMT technology.

Report No.: 93389457-30
Effective date: 2022-11-18
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Issue date: 2022-11-09



Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



/ 77 ELEKTRONIKA KFT.

H-1116 Budapest, Fehérvári út 98.

/ Telefon: +36 1 206 1480

/ Web: E77.HU

Declaration of identity

Urilyzer Cell instrument is a commercial variant of the UriSed mini instrument, which distributes exclusively by Analyticon Biotechnologies GmbH. Urilyzer Cell can perform measurement with Urilyzer Cell Cuvettes.

The two instruments (Urilyzer Cell and UriSed mini) are identical in almost every element:

- Measurement process: The user fills the sample to be tested into disposable cuvettes. After a short centrifugation process, the microscopic optical system of the instrument takes images of the cuvette, which are evaluated by the software running on the built-in computer.
- Optical system: Urilyzer Cell uses the same optical system for imaging, including camera, microscope, objective and illumination.
- Evaluation algorithm: Both devices use the same evaluation module to recognize the same type of urine sediment cells.
- Software: In addition to the evaluation algorithm, the entire software system is the same for both devices, only the logo in the software is different, which in the case of Urilyzer Cell is the Analyticon Biotechnologies GmbH logo.
- Cuvette: Both systems use the same cuvette to test the sample.

The only differences between the two devices are:

- The logo on the instrument
- The logo in the software
- The cuvette sleeve holder, in which the cuvette sleeves can be placed. The cuvettes are inserted into the instrument in a cuvette sleeve. This sleeve has ribs outside that prevent UriSed cuvettes from being used with the Urilyzer Cell.

Urilyzer Cell Cuvettes are the commercial variant of UriSed cuvettes.

Urilyzer Cell Cuvettes and UriSed cuvettes are completely identical, they differ only in the sleeve as described above, but this does not result in any difference in the cuvette itself.

Oliver Babinszki
Quality and Environmental Management Director



EU-DECLARATION OF CONFORMITY

Manufacturer name:	77 Elektronika Műszeripari Kft.
Address:	Fehérvári út 98., H-1116 Budapest
SRN number:	HU-MF-000004266

Product(s) name:	Urilyzer Cell Cuvettes
Reference number:	ULC001
Basic UDI-DI:	59973457CUV9W
GMDN / EMDN	61032 / W02010785
Intended purpose of the device:	Urilyzer Cell Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyse uncentrifuged, human urine samples with Urilyzer Cell urine sediment analysers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.
Classification:	A class

The manufacturer declares under its sole responsibility that the above-mentioned product complies with the requirements of the following legislation (s):

Applicable legalisations:	Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices
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Notified Body name:	N/A
Notified Body address:	N/A
Notified Body Identification Number:	N/A
Conformity assessment procedure:	N/A
EC Certificate of conformity's type, number and validity:	N/A

Budapest, 25.05.2022.

Oliver Babinszki
Quality and Environmental Management Director

77 Elektronika Műszeripari Kft.
1116 Budapest, Fehérvári út 98.
Adószám: 10229064-2-44
BBRT: 10102093-01196703-00000005
36.

Urilyzer Cell Cuvettes

REF

ULC001

Instructions for use

Intended use:

Urilyzer Cell Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyse uncentrifuged, human urine samples with Urilyzer Cell urine sediment analysers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.

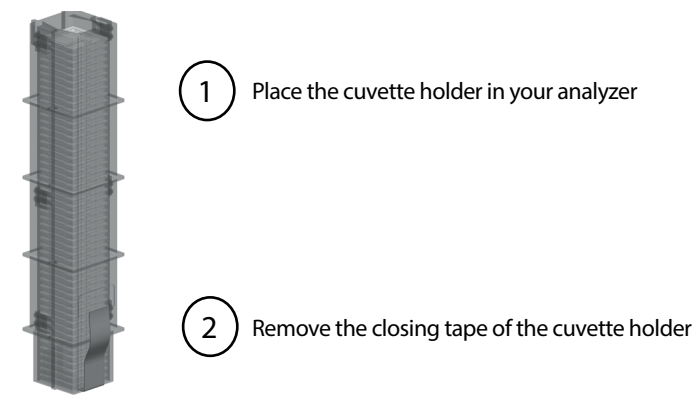
Test principle:

Urilyzer Cell Cuvettes are specimen receptacles allowing for microscopic analysis of urine samples.

Materials not provided:

- Urilyzer Cell urine sediment analyzer
- General laboratory equipment

Using cuvettes:



Environmental Conditions

Storage temperature	0 – 45°C
Transportation temperature	-25°C – 60°C
Transportation humidity	20 – 80 %
Operation temperature	5°C – 40°C
Operational humidity	20 – 80 %

Warnings and cautions

- Do not store cuvettes in direct sunlight
- Do not remove closing tape from the cuvette holder before installing in your analyzer
- Do not remove partially full cuvette holders from your analyzer
- Each cuvette is single use, never perform a test with previously used cuvette
- Since urine is a fluid of human origin, it may be infectious and may bear the possibility of biological risks
- Handle used Urilyzer Cell Cuvettes and urine contaminants with care
- Dispose of waste according to accepted laboratory instructions and procedures
- Use cuvettes before expiration date

Check your analysers instructions for use for details on specimen collection, potential preparatory steps, result calculation, analytical and performance characteristics, interferences, limitations, quality control procedures, specific warnings and cautions

Incident reporting

Inform your Analyticon Biotechnologies service representative and your local competent authority about any serious incidents which may occur when using this product.

Symbols:

- UDI** Unique Device Identifier
- IVD** In vitro diagnostic medical device
- REF** Catalogue Number
- LOT** Lot Number
- CE** The CE mark identifies that the product complies with the applicable directives of the European Union
- Use by
- Temperature Limitation
- Manufacturer
- Keep away from sunlight
- Consult instructions for use
- Humidity limitation
- Caution
- 600 Contents sufficient for 600 tests
- Do NOT Reuse
- Country of origin and manufacturing date
- Distributed by

Version history

Version	Date	Changes
1	2022.04.12.	First release

CE

Manufacturer:

77 Elektronika Kft.
98. Fehérvári út, 1116 Budapest
HUNGARY
www.en.e77.hu
sales@e77.hu
Tel: + 36 1 206 - 1480
Fax: + 36 1 206 - 1481

Distributed by:

Analyticon Biotechnologies GmbH
Am Muehlenberg 10
35104 Lichtenfels, Germany
info@analyticon-diagnostics.com
www.analyticon-diagnostics.com

**For submission at the competent
Authorities of the Republic of Moldova**



Letter of Authorization

WHEREAS, **Analyticon Biotechnologies GmbH**, who is an established, and well-known manufacturer and producer of Medical Diagnostics having production facilities at 35104 Lichtenfels (Germany), Am Muehlenberg 10, do hereby declare that

Sanmedico SRL

A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova

Tel: +373 60 15-57-88

E-Mail: sanmedico.office@gmail.com

is authorized to register, import, promote and sell our urinalysis and hematology products non-exclusively within the territory of the Republic of Moldova as a Distributor for our products. We authorize Sanmedico SRL to overtake the procedures regarding the registration of the mentioned products and the Renewal of expiring Licenses for Sale of our product range of these In-Vitro-Diagnostic products at the Authorities of the Republic of Moldova. Sanmedico SRL is authorized to participate in tenders only in the territory of the Republic of Moldova. This Letter of Authorization is valid for three (3) years from the date of issue. It could be elongated from Analyticon Biotechnologies AG for another period in accordance with Sanmedico SRL. Cancellation must be in writing with a cancellation period of 3 Months for each party.

The construction of this agreement, validity and performance of this agreement and all subsequent agreements shall be exclusively governed by the laws of Germany. This agreement shall be interpreted under German Law. The laws of the Federal Republic of Germany are legally binding; this excludes the validity of the UN purchasing laws, particularly the United Nations treaty on contracts regarding the international sale of moveable property. This is also valid should the DISTRIBUTOR not be of German nationality or his head office be situated outside Germany. The parties submit to the exclusive jurisdiction of the District Courts at Korbach, Postal Code D-34497, Germany / the regional court of the city of Kassel, Germany. This Authorisation letter will replace all other existing Authorisation letters between the parties.

For and on behalf of Analyticon Biotechnologies GmbH
Signed on 14th June 2023, at Lichtenfels (Germany)

Dennis Kasper
Business Area Manager Europe (East) & Africa
Analyticon Biotechnologies GmbH

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Analyticon Biotechnologies GmbH

Scope of certification:

Development, production and distribution of in-vitro diagnostics from the field of urine diagnostics for professional and near-patient applications
Distribution, service and installation of in-vitro-diagnostic analyzers from the field of urine diagnostics.
Distribution of in-vitro diagnostic devices from the field of hematology
Distribution and service of in-vitro-diagnostic analyzers from the field of hematology

Certified location:

Am Mühlenberg 10, 35104 Lichtenfels, Germany
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard.
The conformity was adduced with audit report no. 51519-R1-00.

Certificate registration no.: 51519-14-02_EN
Validity of previous certificate: 2023-03-05

Certificate valid from: 2023-03-06
Certificate valid to: 2025-01-10


Karin Leicht

DEKRA Certification GmbH, Stuttgart, 2023-03-06



Annex to the Certificate No. 51519-14-02

valid from 2023-03-06 to 2025-01-10

The following locations/companies belong to the certificate above:

Headquarters		Scope of certification
Analyticon Biotechnologies GmbH	Am Mühlenberg 10 35104 Lichtenfels Germany	see page 1
at the following locations/at the companies at the following locations		Scopes of certification
1.	Am Teichsberg 10 Lichtenfels-Sachsenberg Germany	Reception, shipping and storage of raw materials, semi-finished goods, finished goods and analyzers from the fields of urine diagnostics and hematology.


Karin Leicht

DEKRA Certification GmbH, Stuttgart, 2023-03-06



Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity – Urine Diagnostics



Analyticon Biotechnologies GmbH

**Am Mühlenberg 10,
35104 Lichtenfels, Germany**

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte für die In-vitro-Diagnostik
We declare under our sole responsibility that the in vitro diagnostic medical devices

Bezeichnung und Artikelnummer: siehe Anhang
Description and article number: see annex

mit folgender Klassifizierung nach der Richtlinie über In-Vitro-Diagnostika 98/79/EG
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

- () Produkt der Liste A, Anhang II / Device of List A, Annex II
- () Produkt der Liste B, Anhang II / Device of List B, Annex II
- () Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist /
Device for self-testing not listed in Annex II
- (X) Sonstiges Produkt / Other device

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar
sind.

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

Konformitätsbewertungsverfahren
Conformity assessment procedure

IVD 98/79/EG, Artikel 9 (1) und Anhang III /
IVD 98/79/EC Article 9 (1) and Annex III

EDMA-Code und Registrierungsnummer
EDMS-Code and Registration-No.

siehe Anhang
see annex

Konformitätsbewertungsstelle

nicht erforderlich, die Bewertung wurde in
Eigenverantwortung des Herstellers durchgeführt

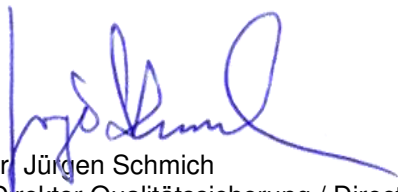
Notified Body (if consulted)

*not applicable, evaluation was carried out under
the manufacturer's own responsibility*

Ort, Datum / *Place, date*

Name und Funktion / *Name and function*

Lichtenfels, 18.01.2023


Dr. Jürgen Schmich
(Direktor Qualitätssicherung / Director Quality Assurance)

Test strips visual and semi-automated systems

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® 11SYS	93100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS	93150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120B	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3	93108A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GP	93104	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GPK	93105	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150BC	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL PLUS	94120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9 PLUS	94115	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94250	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94200	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5SYS PLUS	94109	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94517	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94117	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94535	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94135	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94508	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94108	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Glu PLUS	94501	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Nitrit PLUS	94506	11.70.02.02.00	DE/CA30/00017200
CombiScreen® mALB / CREA	94025	11.70.02.02.00	DE/CA30/00017200

Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity – Urine Diagnostics



Analyticon Biotechnologies GmbH

**Am Mühlenberg 10,
35104 Lichtenfels, Germany**

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We declare under our sole responsibility that the in vitro diagnostic medical devices

Bezeichnung und Artikelnummer: siehe Anhang
Description and article number: see annex

mit folgender Klassifizierung nach der Richtlinie über In-Vitro-Diagnostika 98/79/EG
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sind.

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Konformitätsbewertungsverfahren
Conformity assessment procedure

IVD 98/79/EG, Artikel 9 (1) und Anhang III /
IVD 98/79/EC Article 9 (1) and Annex III

EDMA-Code und Registrierungsnummer
EDMS-Code and Registration-No.

siehe Anhang
see annex

Konformitätsbewertungsstelle

nicht erforderlich, die Bewertung wurde in
Eigenverantwortung des Herstellers durchgeführt

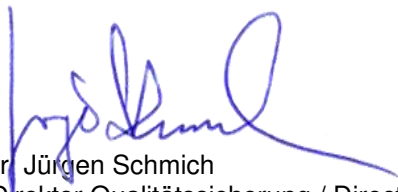
Notified Body (if consulted)

*not applicable, evaluation was carried out under
the manufacturer's own responsibility*

Ort, Datum / *Place, date*

Name und Funktion / *Name and function*

Lichtenfels, 18.01.2023


Dr. Jürgen Schmich
(Direktor Qualitätssicherung / Director Quality Assurance)



Analyticon Biotechnologies GmbH
Am Mühlberg 10,
35104 Lichtenfels, Germany

Anhang zur Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity, Annex – Urine Diagnostics

CombiScreen Urine Controls

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® Dip Check	93010	11.50.90.02.00	DE/CA30/00041388
CombiScreen® Drop Check	93015	11.50.90.02.00	DE/CA30/00041388

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 1 of 7

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

CombiScreen® Drop Check Level 1

Product group: Endprodukt / Endproduct

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.3. Details of the supplier of the safety data sheet**

Company name: Analyticon® Biotechnologies GmbH
Street: Am Mühlenberg 10
Place: D-35104 Lichtenfels
Telephone: +49 (0) 6454/7991-0 Telefax: +49 (0) 6454/7991-30
E-mail: support@analyticon-diagnostics.com
Contact person: Zentrale Telephone: +49 (0) 6454/7991-0
Internet: http://www.analyticon-diagnostics.com

1.4. Emergency telephone number:

Zentrale: +49 (0) 6454/7991-0

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements**Regulation (EC) No 1272/2008****Special labelling of certain mixtures**

Restricted to professional users.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
	Human Source Material			10-60 %

Full text of H and EUH statements: see section 16.

Further Information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 2 of 7

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth immediately and drink plenty of water.

Rinse mouth thoroughly with water.

Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

The product itself does not burn.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up**Other information**

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

Take up dust-free and set down dust-free.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Use only in well-ventilated areas.

The floor should be leak tight, jointless and not absorbent.

All work processes must always be designed so that the following is excluded:

Advice on protection against fire and explosion

Usual measures for fire prevention.

When using do not smoke.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 3 of 7

Wash hands before breaks and after work.

Further information on handling

When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.

Keep only in the original container in a cool, well-ventilated place.

Further information on storage conditions

2 8

Protect against:

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.2. Exposure controls****Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. EN ISO 374

Breakthrough times and swelling properties of the material must be taken into consideration.

Skin protection

Wear suitable protective clothing. Suitable protective clothing:

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at:

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

Colour:

Odour: characteristic

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

not determined

boiling range:

Flammability:

not determined

not applicable

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

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Lower explosion limits:	not determined
Upper explosion limits:	not determined
Decomposition temperature:	not determined
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

Self-ignition temperature

Solid:	not determined
Gas:	not applicable

Other safety characteristics

Evaporation rate:	not determined
Solid content:	not determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

No information available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Sensitising effects

No information available.

STOT-repeated exposure

No information available.

Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to Directive 1999/45/EC.

11.2. Information on other hazards

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Endocrine disrupting properties

No information available.

SECTION 12: Ecological information**12.1. Toxicity**

The product has not been tested.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No data available

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Dispose of waste according to applicable legislation. Dispose of waste according to applicable legislation.

Dispose of waste according to "Kreislaufwirtschafts- und Abfallgesetz (KrW-/AbfG)".

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

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Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information**

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 2,11.

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
 (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service
 LC50: Lethal concentration, 50%
 LD50: Lethal dose, 50%

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations. The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing,

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transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

CombiScreen® Drop Check Level 2

Product group: Endprodukt / Endproduct

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.3. Details of the supplier of the safety data sheet**

Company name: Analyticon® Biotechnologies GmbH
 Street: Am Mühlenberg 10
 Place: D-35104 Lichtenfels
 Telephone: +49 (0) 6454/7991-0 Telefax: +49 (0) 6454/7991-30
 E-mail: support@analyticon-diagnostics.com
 Contact person: Zentrale Telephone: +49 (0) 6454/7991-0
 Internet: http://www.analyticon-diagnostics.com

1.4. Emergency telephone number:

Zentrale: +49 (0) 6454/7991-0

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements**Regulation (EC) No 1272/2008****Special labelling of certain mixtures**

Restricted to professional users.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
	Human Source Material			10-60 %

Full text of H and EUH statements: see section 16.

Further Information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

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After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth immediately and drink plenty of water.

Rinse mouth thoroughly with water.

Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

The product itself does not burn.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up**Other information**

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

Take up dust-free and set down dust-free.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Use only in well-ventilated areas.

The floor should be leak tight, jointless and not absorbent.

All work processes must always be designed so that the following is excluded:

Advice on protection against fire and explosion

Usual measures for fire prevention.

When using do not smoke.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

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Wash hands before breaks and after work.

Further information on handling

When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.

Keep only in the original container in a cool, well-ventilated place.

Further information on storage conditions

2 8

Protect against:

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.2. Exposure controls****Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. EN ISO 374

Breakthrough times and swelling properties of the material must be taken into consideration.

Skin protection

Wear suitable protective clothing. Suitable protective clothing:

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at:

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

Colour:

Odour: characteristic

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

not determined

boiling range:

Flammability:

not determined

not applicable

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Lower explosion limits:	not determined
Upper explosion limits:	not determined
Decomposition temperature:	not determined
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

Self-ignition temperature

Solid:	not determined
Gas:	not applicable

Other safety characteristics

Evaporation rate:	not determined
Solid content:	not determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

No information available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Sensitising effects

No information available.

STOT-repeated exposure

No information available.

Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to Directive 1999/45/EC.

11.2. Information on other hazards

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Endocrine disrupting properties

No information available.

SECTION 12: Ecological information**12.1. Toxicity**

The product has not been tested.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No data available

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Dispose of waste according to applicable legislation. Dispose of waste according to applicable legislation.

Dispose of waste according to "Kreislaufwirtschafts- und Abfallgesetz (KrW-/AbfG)".

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

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Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information**

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 2,11.

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
 (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service
 LC50: Lethal concentration, 50%
 LD50: Lethal dose, 50%

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations. The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing,

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transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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CombiScreen® 11SYS

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Product code: 93150

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

CombiScreen® 11SYS

Product group: Endprodukt / Endproduct

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.3. Details of the supplier of the safety data sheet**

Company name:	Analyticon® Biotechnologies GmbH		
Street:	Am Mühlenberg 10		
Place:	D-35104 Lichtenfels		
Telephone:	+49 (0) 6454/7991-0	Telefax:	+49 (0) 6454/7991-30
E-mail:	support@analyticon-diagnostics.com		
Contact person:	Zentrale	Telephone:	+49 (0) 6454/7991-0
Internet:	http://www.analyticon-diagnostics.com		

1.4. Emergency telephone number: Zentrale: +49 (0) 6454/7991-0

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Hazardous components**

none (according to Regulation (EC) No 1907/2006 (REACH))

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth thoroughly with water.

Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

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5.1. Extinguishing media**Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings. The product itself does not burn.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Avoid dust formation.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up**Other information**

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Take up dust-free and set down dust-free.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Use only in well-ventilated areas.

The floor should be leak tight, jointless and not absorbent.

All work processes must always be designed so that the following is excluded:

Advice on protection against fire and explosion

Usual measures for fire prevention.

When using do not smoke.

Advice on general occupational hygiene

Take off contaminated clothing. When using do not eat or drink. Wash hands before breaks and after work.

Further information on handling

When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep only in the original container in a cool, well-ventilated place.

Further information on storage conditions

15 25

Protect against:

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters**Occupational exposure limit values**

CAS No	Name of agent	ppm	mg/m ³	fib/cm ³	Category	Origin
7664-38-2	Orthophosphoric acid	-	1		TWA (8 h)	
		-	2		STEL (15 min)	

8.2. Exposure controls**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. EN ISO 374

Breakthrough times and swelling properties of the material must be taken into consideration.

Skin protection

Wear suitable protective clothing.

Respiratory protection

Respiratory protection necessary at:

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

Colour:

Odour: characteristic

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

not determined

boiling range:

Flammability:

not determined

not applicable

Lower explosion limits:

not determined

Upper explosion limits:

not determined

Decomposition temperature:

not determined

pH-Value:

No data available

Water solubility:

The study does not need to be conducted
because the substance is known to be
insoluble in water.

Solubility in other solvents

Buffer

Partition coefficient n-octanol/water:

not determined

Vapour pressure:

not determined

Density:

not determined

Relative vapour density:

not determined

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

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Product code: 93150

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9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

Self-ignition temperature

Solid:

not determined

Gas:

not applicable

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

No information available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

No information available.

Sensitising effects

No information available.

Carcinogenic/mutagenic/toxic effects for reproduction

No information available.

STOT-repeated exposure

No information available.

Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

11.2. Information on other hazards**Endocrine disrupting properties**

No information available.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

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SECTION 12: Ecological information**12.1. Toxicity**

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

The product has not been tested.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Dispose of waste according to "Kreislaufwirtschafts- und Abfallgesetz (KrW-/AbfG)".

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**Land transport (ADR/RID)****Other applicable information (land transport)**

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)**Other applicable information (inland waterways transport)**

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)**Other applicable information (marine transport)**

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)**Other applicable information (air transport)**

No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

Page 6 of 6

not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 75

2004/42/EC (VOC): 0,009 %

National regulatory information

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 11.

Abbreviations and acronymsADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Skin Corr: Skin corrosion

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Authorization Certificate



Vitalie Goreacii

SANMEDICO SRL

This is to certify that the above named general manager has successfully completed the full application and technical training which was specifically prepared and carried out on the Analyticon Biotechnologies GmbH equipment mentioned below on May 22nd to 23rd, 2023

Urilyzer[®] Cell

We hereby state that the general manager is authorized and qualified by Analyticon to do installation, operation, user and technical training, service and maintenance of the equipment listed above.

Analyticon
Biotechnologies GmbH
Customer Support & Trainings



Nathalie Mütze
Manager Customer Support

Nils Albrecht
Customer Support

CS_FB_OR_9999

Urilyzer® 100 Pro



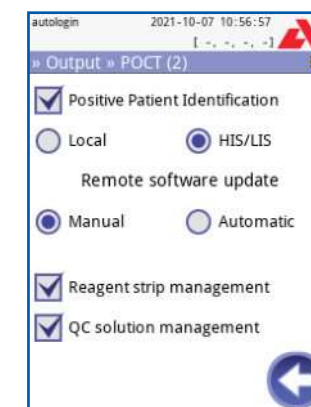
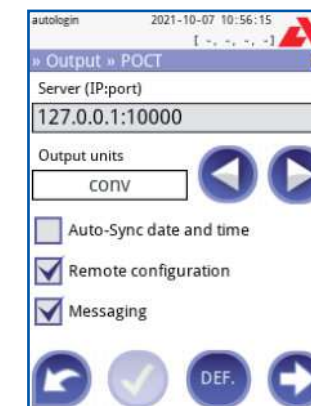
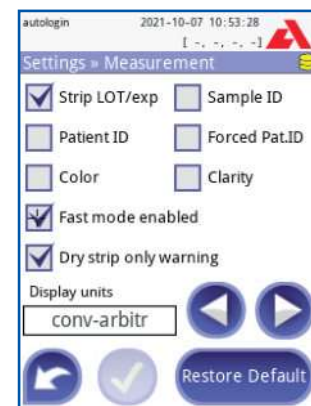
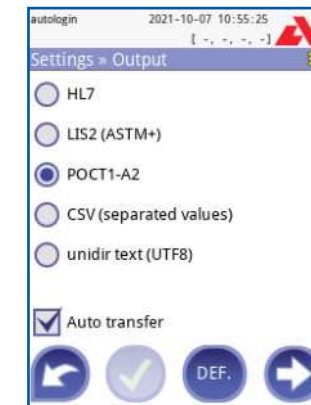
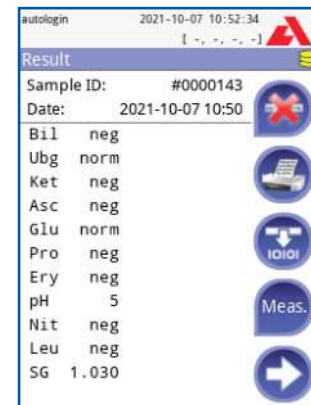
**A new way
in urinalysis**



- Easy-to-use
- Smart and safe operation
- Extended connectivity capabilities
- POCT-features

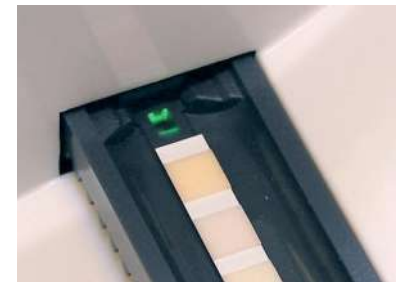
Easy-to-use

- A Start-Up Wizard leads the operator through the user-defined settings upon first start of the device.
- Automatic start of the measurement after placing the urine test strip allows hygienic and clean operation of the analyzer
- Positive results, reminders and warnings are shown in color (e.g. red or yellow) and can be easily identified
- The user interface offers a high level of customization with flexible testing and reporting options



Connectivity capabilities

- Data can be transferred via serial connection or Ethernet
- A variety of interfaces for connecting external barcode scanner and/or keyboard (USB or PS2)
- Implemented protocols: HL7, LIS2 (ASTM+), POCT1-A2



CombiScreen® DIP Check

Catalog No. 93010

2 x 15 mL

Lot No. Y 686

Expiry 2020/05



Analyte	Analyticon CombiScreen® Urine Test Strips		Instrumental (Analyticon CombiScan® / Urilizer®)	
	Visual		Level 1	Level 2
Ascorbic Acid	Negative	Negative	Negative	Negative – 20 mg/dl Negative – 1+
Bilirubin	Negative	1+ – 3+	Negative	1+ – 4 mg/dl 10 – 20 µmol/L 1+ – 3+
Blood	Negative *)	10 – 300 Eryul 1+ – 3+	Negative *)	10 – 300 Eryul 1+ – 3+
Glucose	Normal	50 – 1000 mg/dl 2.8 – 50 mmol/L	Normal	50 – 1000 mg/dl 2.8 – 50 mmol/L 1+ – 5+
Ketones	Negative	(+) – 3+	Negative	10 – 300 mg/dl 1.0 – 30 mmol/L 0.1 – 3+
Leucocytes	Negative	25 – 500 Leuyl	Negative	25 – 500 Leuyl 1+ – 3+
Nitrite	Negative *)	Positive	Negative *)	Positive
pH	5 – 6	7 – 9	5 – 7	6 – 9
Protein	Negative	30 – 500 mg/dl	Negative	30 – 500 mg/dl 0.3 – 5.0 g/L 1+ – 3+
Specific Gravity	1.020 – 1.030	1.000 – 1.015	1.015 – 1.030	1.000 – 1.030

Level 1

Level 2

Instrumental (Analyticon CombiScan® / Urilizer®)

Level 1

Level 2

Smart and safe operation

- Tracking of LOT-No. for urine strips and quality control solutions
- Data management provides multiple filter options
- QC ranges can be entered via QR-Code
- Automated QC analysis with customizable QC test reminders including lockout function
- System allows the allocation of different security levels to individual users

POCT1-A2 features

- Validated for use with Siemens UniPOC™ and POCcelerator™*
- Remote configuration via middleware
- Automated synchronization of date and time via the middleware
- Messaging function allows the POCT datamanager to send messages to addressed operators or instruments
- Positive Patient Identification (PPID)
- Remote software update
- Test strip management
- QC solution management
- Proficiency test feature

* please contact us for other middleware options

Technical Specifications

Type	Semi-automated urine test strip analyzer
Measurement technology	Reflectance photometer with 4 discrete wavelengths 505, 530, 620, 660 nm
Parameters	11 Parameter: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes, Specific Gravity 7 Parameter: Ketones, Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes, pH 5 Parameter: Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes 2 Parameter: Albumin, Creatinine
Throughput	Up to 50 tests/hour (in normal mode) Up to 120 tests/hour (in fast mode)
Data storage	Patient database: 3.000 tests QC database: 1.000 tests
Display	3.5" QVGA touchscreen LCD
Interfaces	Serial RS232, USB Type A, USB Type B, PS2 (external keyboard, barcode reader), Ethernet
Dimensions	208 x 290 x 80 mm (WxDxH)
Weight	1.2 kg
Power supply	7.5 V DC / 3 A
Operating environment	Temperature: +15°C to +32°C Relative humidity (non-condensing): 30% to 80% Atmospheric pressure: 70 kPa to 106 kPa
Printer	Built-in thermal printer
Barcode reader	External
Protocols	LIS2 (ASTM+), HL7, POCT1-A2
Features	• Start-Up Wizard upon first usage • Operator Management with advanced system security options • Test strip & QC Management (full traceability via LOT and Expiry entry) • Data Management, Power Management • Autostart of measurement (automatic strip detection) • Automatic printout or transfer of result • Flexible advanced information entry (e.g. sample color and turbidity) • Flexible advanced testing and reporting options (e.g. sediment recommendation flag)
Languages	Czech, Danish, English, Finish, French, German, Greek, Hungarian, Italian, Norwegian, Polish, Romanian, Russian, Spanish, Swedish

Art.-No.: UL0100Pro

Consumables

	Urine test strips	Pack size	Art.-No.	
	CombiScreen® 11SYS PLUS	100/150 strips	94100/94150	
	CombiScreen® 7SYS PLUS	100/150 strips	94110/94110A	
	CombiScreen® 5SYS PLUS	100 strips	94109	
	CombiScreen® 11SYS	100/150 strips	93100/93150	
	CombiScreen® mALB / CREA	25 strips	94025	
	Control	Pack size	Art.-No.	
	CombiScreen® Dip Check	2 x 15 ml	93010	
	CombiScreen® Drop Check	2 x 5 ml	93015	

Distributor information



Analyticon Biotechnologies GmbH

Am Muehlenberg 10
35104 Lichtenfels - Germany
Phone: +49 6454 7991-0
info@analyticon-diagnostics.com
www.analyticon-diagnostics.com

CombiScreen® Urine Control



CombiScreen® Dip Check

Art.-No. 93010

Ready-to-use dipper control

2 x 15 ml (Level 1 + Level 2)

Open vial stability (at 2–8 °C) of 75 days or 20 determinations (whichever occurs first)

CombiScreen® Drop Check

Art.-No. 93015

Ready-to-use dropper control

2 x 5 ml (Level 1 + Level 2)

Open vial stability of 18 months (2–8 °C) or 30 days (20–25 °C)

Features:

- Based on human standard material
- Suitable for use in POC testing
- Shatter proof vials (polystyrene)
- 2D-barcode on tube vial for direct entry of lot number and target values into Urilyzer® 100 Pro and Urilyzer® 500 Pro instruments
- Target values for CombiScreen® test strips as well as other test strip brands
- Parameters: Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, pH, Nitrite, Leukocytes, Specific Gravity, Creatinine, Microalbumin and hCG
- Qualitative hCG values

CombiScreen® urine controls cover a wide range of analytes, including pregnancy markers and Microalbumin. The controls are designed for use in manual and automated methods, to monitor the performance of a variety of urine test strips.

Analyticon Biotechnologies GmbH

Am Muehlenberg 10
35104 Lichtenfels - Germany
Phone: +49 6454 7991-0
info@analyticon-diagnostics.com
www.analyticon-diagnostics.com

agile - affordable - accurate

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH
Ludwig-Erhard-Ring 3,
15827Blankenfelde-Mahlow, Germany
Tel: +49 33 70 83 55 030
Email: amug@atlas-medical.com

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area
P. O. Box 204, Amman 11512, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Agent: San Medico
Republic of Moldova, city Chisina
+37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Moldova

Appointment Conditions:

1. This appointment is valid for 3 year from the above mentioned date.
2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer
General Manager
Haya Amawi



Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Germany. Tel: +49 33 70 83 55 030
Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK. Tel: +44 1223 858 910
Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11512, Jordan

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

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

pour les activités
for the activities

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

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

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

Voir addendum

See addendum

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

ISO 13485: 2016

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

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

Etabli le / Issued on : October 9th, 2023

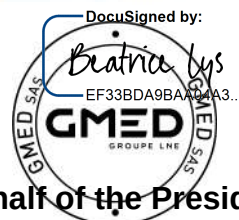


Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36655-2

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

Renouvelle le certificat 36655-1



On behalf of the President
Béatrice LYS
Technical Director

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

French version :

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

English version:

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

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

French version:

Siège social, responsable de la mise sur le marché

English version:

Headquarter, legal manufacturer

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

French version:

Conception, fabrication et contrôle final

English version:

Design, manufacture and final control

2 sites / 2 sites

DocuSigned by:
Beatrice Lys
FF33BDA88AA04A3...
GMED
GROUPE LNE

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

RPR Carbon Antigen

IVD For In-Vitro diagnostic and professional use only

2°C 8°C
Store at 2 to 8 °C

*INTENDED USE

A manual rapid plasma reagin carbon test for the qualitative and semi-quantitative detection of non-treponemal antibodies against Syphilis in human serum and plasma to provide serological evidence of past/current Syphilis infections when preceded by a positive treponemal test. Not to be used as a screening tool for blood or tissue donations.

INTRODUCTION

Syphilis is a disease caused by infection with the spirochete *Treponema pallidum*. The infection is systemic and the disease is characterized by periods of latency. These features, together with the fact that *T. pallidum* cannot be isolated in culture, mean that serologic techniques play a major role in the diagnosis and follow-up of treatment for syphilis.

Syphilis is categorized by an early primary infection in which patients may have non-specific symptoms, and potentially, genital lesions. Patients tested by serology during the primary phase may be negative for antibodies, especially if testing is performed during the first 1 to 2 weeks after symptom onset. As the disease progresses into the secondary phase, antibodies to *T. pallidum* reach peak titers, and may persist indefinitely regardless of the disease state or prior therapy. Therefore, detection of antibodies to nontreponemal antigens, such as cardiolipin (a lipoidal antigen released by host cells damaged by *T. pallidum*) may help to differentiate between active and past syphilis infection. Nontreponemal antibodies are detected by the rapid plasma reagin (RPR) assay, which is typically positive during current infection and negative following treatment or during late/latent forms of syphilis.

PRINCIPLE

RPR utilises carbon particles coated with cardiolipin antigen to detect reagin antibodies present in serum or plasma of syphilitic persons.

Specimens that contain reagin cause aggregation of the carbon particles which appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non-aggregated pattern which may form buttons in the centre of the test area.

MATERIALS

MATERIALS PROVIDED

- **RPR carbon antigen reagent:** A particulate carbon suspension coated with lipid complexes, with 0.95 g/L sodium azide.
- **Positive Control:** Human syphilitic serum reactive with the test reagent, with 0.95 g/L Sodium azide. **(Optional).**
- **Negative control:** non-reactive phosphate buffer containing 5% BSA pH7.4, with 0.1% of Sodium azide. **(Optional).**
- **RPR test cards or white glass slide (Optional).**
- **Plastic sticks (Optional).**
- **Package insert.**

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Rotator (100rpm).
- Timer.
- Calibrated micropipettes and tips.

PACKAGING CONTENT

REF 8.00.18.0.0100 (2mL Reagent, 1x0.5mL Positive Control, 1x0.5mL Negative Control)

REF 8.00.18.0.0500 (10mL Reagent, 1x1mL Positive Control, 1x1mL Negative Control)

REF 8.00.18.3.1000 (2x10mL Reagent, 1x2mL Positive Control, 1x2mL Negative Control)

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.
- *Do Not Freeze.
- *Signs of deterioration:
 - RPR Carbon: Visible agglutination.
 - Controls: Presence of particles and turbidity.

PRECAUTIONS AND WARNINGS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- *The test is not for near-patient or self-testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all negative and positive in the manner as patient specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Components of different human origin have been tested and found to be negative for the presence of antibodies anti- HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
- *Do not touch, drink, or ingest the reagent.

- *Do not use black glass slides during testing.
- *Perform the test in a well-lit area with good visibility.
- *Failure in following the instructions may give incorrect results or face safety hazards.
- *Wash the area of contact with water immediately if contact occurs.
- *Wash of the hands and the test table top with water and soap.
- *Do not use the reagent if displaying any signs of deterioration.
- *Always use a fresh pipette tip and stirring sticks for each test.
- *Handle the used disinfectant with care.
- *Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- *Do not use the reagents if the label is missing, damaged, or unclear.
- *Do not use leaked vials and making proper disposal of them.
- *Use forceps, scoops, or other mechanical devices for removing broken glass from the working area. A dustpan and brush should be used to clean up shards/small pieces of broken glass. Broken glass must be disposed of in a sharps container.
- *The reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- Fresh serum or plasma. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- *Samples may be stored at 2-8° C for up to 7 days. For long term storage sera should be stored at -20° C up to 30 days.

REAGENT PREPARATION

RPR reagent is ready to use. No preparation is required.

PROCEDURES

QUALITATIVE PROCEDURE

- **Mix well the RPR reagent before use.**
- 1. Bring the reagents and samples to room temperature.
- 2. Dispense **50 µL of each sample** into a separate circle on the card. Use a separate tip for each sample.
- 3. Dispense **1 drop of each of positive and negative controls** into two additional circles.
- 4. Gently shake the dispensing vial and slightly press to remove air bubbles from the needle and the drop obtained is correct.

- Dispense **1 drop (17.5 µl)** of **RPR antigen** to each circle next to the sample to be tested.
- *Close the reagent vial tightly.
- *Spread the specimen evenly over the test circle.
- Place the card on a mechanical rotator and rotate at 100 r.p.m. for 8 minutes.
- Observe macroscopically for agglutination within a minute after removing the card from the rotator.

SEMI-QUANTITATIVE PROCEDURE

- Mix well the RPR reagent before use.**
- Make doubling dilutions from Undiluted to 1:16 normal saline.
 - Place 50 µl of each dilution in to a separate circle on the test card.
 - Spread each dilution evenly over the test circle.
 - Continue as from Qualitative procedure .
- The titer of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

INTERPRETATION OF TEST RESULTS

- Strong Reactive:** Large clumps of carbon particles with a clear background.



- Reactive:** Large clumps of carbon particles somewhat more disperse than Strong Reactive pattern.



- Weak Reactive:** Small clumps of carbon particles with light grey background.



- Trace Reactive:** Slight clumping of carbon particles typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the test circle.



- Non-Reactive:** Typically a smooth grey pattern or a button of non-aggregated carbon particles in the centre of the test circle.



***LIMITATION OF THE TEST**

- Pregnancy may give a false positive reaction.
- Hepatitis and Brucellosis may give a false positive reaction.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE CHARACTERISTICS

Sensitivity: 100%.

Specificity: 100%.

Precision: 100%

Hook effect: no prozone effect up to the titer level studied: 1/16.

Interferences: There is no effect from Hemoglobin/Bilirubin and Rheumatoid factor on the results of RPR carbon antigen at the studied concentrations:

Bilirubin: ≤15 mg/dL.

Hemoglobin: ≤10 g/L.

Rheumatoid factor: ≤300 IU/ml.

REFERENCES

- Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.

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Website: www.atlas-medical.com

PPI2280A01
Rev C (27.03.2024)

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

***: Indication of the introduced modifications.**

CE Declaration of Conformity

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

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

Declare our responsibility that the following product:

Product Code	Product Name	Class	GMDN code
8.00.18.0.0005	RPR Carbon Antigen Reagent, 5 ml/vial	General-IVD	32450
8.00.18.2.1000	RPR Carbon Antigen 1000ml/bottle	General-IVD	32450
8.00.18.0.0050	RPR Carbon Antigen Kit, 50 Tests	General-IVD	32450
8.00.18.1.0050	RPR Carbon Antigen Kit, 50 Tests, White Glass Slide.	General-IVD	32450
8.00.18.2.0500	RPR Carbon Antigen Kit, 500 Tests (2ml latex, 2x0.5 ml control) Without card.	General-IVD	32450
8.00.18.3.0500	RPR Carbon Antigen Kit, 500 Tests (10ml latex, 2x0.5 ml control) Without card, stirring sticks.	General-IVD	32450
8.00.18.0.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.2.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control +White Glass slide stirring sticks)	General-IVD	32450
8.00.18.0.0025	RPR Carbon Antigen Kit, 25 Tests (0.5ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.0.0150	RPR Carbon Antigen Kit, 150 Tests	General-IVD	32450
8.00.18.0.0200	RPR Carbon Antigen Kit, 200 Tests	General-IVD	32450
8.00.18.0.0250	RPR Carbon Antigen Kit, 250 Tests	General-IVD	32450

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10
	September.2021	06.09.2021		08.02.2011

Amin Al-Habashat
 RA Manager

Declaration Ref No: DC21-0193

8.00.18.0.0500	RPR Carbon Antigen Kit,500 Tests	General-IVD	32450
8.00.18.0.1000	RPR Carbon Antigen Kit, 1000 Tests	General-IVD	32450
8.00.18.4.0500	RPR Carbon Antigen Kit,500 Tests (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.5.0500	RPR Carbon Antigen Kit, 500 Tests, (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.8.0500	RPR Carbon Antigen 500 Test (10ml reagent) without Control's.	General-IVD	32450
8.00.18.9.0050	RPR Carbon Antigen Kit, (5x10ml Reagent,2x2ml Control) , white glass Slide, Stirring Stick.	General-IVD	32450
8.33.04.0.0001	RPR Positive control	General-IVD	32450
8.33.04.1.0001	RPR Positive control ,Bulk	General-IVD	32450
8.33.04.0.0100	RPR Positive control(100ml/vial)	General-IVD	32450
8.33.04.0.0500	RPR Positive control(500ml/bottle)	General-IVD	32450
8.33.08.0.0001	RPR Negative control	General-IVD	32450

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate:

Certificate N^o.: 36655 rev 1

Expiry Date: October 8th.2023

and complies with the essential requirements of
In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016

**EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,
EN 13612:2002, EN 13641:2002 , EN 13975:2003, ISO 13485:2016**

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

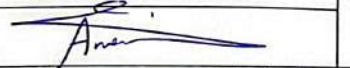
Manufacturer

Atlas Medical GmbH

Ludwig-Erhard-Ring 3

15827 Blankenefelde-Mahlow Germany.



Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021		

Amir Al-Habash
RA Manager

TO WHOM IT MAY CONCERN

To any governmental departments,
registration and/or trade offices in MOLDOVA

Distribution Authorisation Letter

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

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

Sanmedico will provide the following information to TECO GmbH when so required in relation to its market surveillance activities:

Reporting of incidents to TECO must take place within 3 working days
Serial number of the device, exact location of the device and the user.

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

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

Products:

- | | |
|--|---|
| • Coatron M1 | Semi-automated 1-channel Coagulometer (out of production) |
| • Coatron M2 | Semi-automated 2-channel Coagulometer (out of production) |
| • Coatron X Eco | Semi-automated 1-channel Coagulometer |
| • Coatron X Pro | Semi-automated 2-channel Coagulometer |
| • Coatron X Top | Semi-automated 4-channel Coagulometer |
| • Coatron A4 | Fully automated Coagulometer, 4 optic channels |
| • Coatron A6 | Fully automated Coagulometer, 6 optic channels |
| • Coatron A6 plus | Fully automated Coagulometer, 6 optic channels |
| all instruments with complete accessory, consumables and spare parts | |
| • Hemostasis Reagents | Complete product line |

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

TECO Medical Instruments Production+Trading GmbH


Christian Hoetzl
General Management



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





KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Doc#200/12-2023

Hersteller / Manufacturer:

**TECO Medical Instruments
Production + Trading GmbH**

Adresse / Address:

Dieselstrasse 1, 84088 Neufahrn, Germany

Marktakteur / Actor ID SRN:

DE-MF-000022642 <https://ec.europa.eu>

Wir erklären hier für die im Anhang A (Seite 2 – 24 IVD Produkte) spezifizierten Produkte dass sie gemäß der Richtlinie für In-vitro-Diagnostika Medizinprodukte 98/79/EC klassifiziert sind als allgemeine IVD.

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

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

We declare herewith, for the products - specified in Annex A (page 2 /- 24 IVD) that they are classified as general IVD according to the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

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

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

Sie entsprechen den anwendbaren Anforderungen der Richtlinie:

They meet applicable requirements of:

Richtlinie 98/79/EG über In-vitro-Diagnostika
klassifiziert gemäß Artikel 9 als "alle anderen Produkte"

Directive 98/79/EC on in-vitro-diagnostic medical devices
classified according to article 9 as „all other products“

Die Qualitätssicherung entspricht den Anforderungen der
Richtlinie 98/79/EG über In-vitro-Diagnostika
für diese Art von Produkten.

The Quality Assurance is in accordance with the requirements
of Directive 98/79/EC on in-vitro-diagnostic medical devices
for those kind of products.

Der implementierte QM-Prozess entspricht der EN ISO 13485:2021

The implemented QM Process complies with EN ISO 13485:2021

Die vorstehende Konformitätserklärung ist gültig für alle Chargen
dieser Produkte, die nach dem Datum der Unterzeichnung in Verkehr
gebracht wurden.

The above mentioned declaration of conformity is valid for all lots
of this product, which are distributed after the date of signature.

Das Konformitätsbewertungsverfahren entspricht Anhang III
der Richtlinie 98/79/EG über In-vitro-Diagnostika
für diese Art von Produkten.

The conformity assessment procedure complies with Annex III
of Directive 98/79/EC on in-vitro-diagnostic medical devices
for those kind of products.

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

Neufahrn, 2023-12-20

Christian Hötzel
Verantwortliche Person / PRRC

Doc#200/12-2023

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Directive 98/79/EC Annex A

Übrige Produkte – Reagenzien für In-vitro-Diagnostika
Other products – Reagents for in vitro diagnostic – general IVD

Pos.	Article No	Tradename	Unit	Generic Device Term	EMDN / GMDN Code EUDAMED DI
1	A0230-010	TEClot PT-S (Quick)	5x2ml	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-010WW
2	A0230-040	TEClot PT-S (Quick)	10x4ml	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-040X7
3	A0230-100	TEClot PT-S (Quick)	10x10ml	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-100WY
4	A0260-050	TEClot PT-B (Owren)	5x10ml	Prothrombin time RT & POC	W0103020801 / 55986 B-PTB-A0260-050G2
5	A0320-050	TEClot APTT-S	10x5ml	Activated partial thromboplastin time	W0103020102 / 55982 B-APTT-A0320-050AM
6	A0401-020	TEClot TT	10x2ml	Thrombin time / reptilase / batroxbin time	W0103020103 / 55988 B-TT-A0401-0207P
7	A0511-020	TEClot FIB	10x2ml	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-020N2
8	A0511-050	TEClot FIB	10x5ml	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-050NB
9	C1010-020	TEChrom AT	6x6ml reagent FXa 3x3 ml substrate	Antithrombin	W0103020602 / 56156 B-AT-C1010-020HL
10	D2010-012	Red D-Dimer	3x4ml latex 3x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2010-0126W
11	D2020-005	Blue D-Dimer LC	1x5ml latex LC 1x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2020-0057E
12	P8001-005	TECal N	5x1ml	Calibration plasma for haemostasis	W0103020701 / 45786 B-CAL-P8001-005X8
13	P8200-005	TECal DD	5x1ml	Calibration plasma for haemostasis	W0103020701 / 47348 B-CAL-P8200-005XX
14	P6001-010	TEControl N	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6001-010H7
15	P6101-010	TEControl A	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6101-010HQ
16	P6201-010	TEControl A Plus	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6201-010J9
17	P5001-010	TEClot Factor II	10x1ml	Coagulation factor ii (prothrombin)	W0103020202 / 30542 B-FAC-II-P5001-010ML
18	P5101-010	TEClot Factor V	10x1ml	Coagulation factor v	W0103020204 / 30544 B-FAC-V-P5101-010AN
19	P5201-010	TEClot Factor VII	10x1ml	Coagulation factor vii	W0103020205 / 30545 B-FAC-VII-P5201-0107B
20	P5301-010	TEClot Factor VIII	10x1ml	Coagulation factor viii	W0103020207 / 30547 B-FAC-VIII-P5301-01097
21	P5401-010	TEClot Factor IX	10x1ml	Coagulation factor ix	W0103020208 / 30548 B-FAC-IX-P5401-0106C
22	P5501-010	TEClot Factor X	10x1ml	Coagulation factor x	W0103020209 / 30549 B-FAC-X-P5501-010EQ
23	P5601-010	TEClot Factor XI	10x1ml	Coagulation factor xi	W0103020210 / 30551 B-FAC-XI-P5601-010A8
24	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



Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



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

CERTIFICATE

for: **Mr. Vitalie Goreacii**

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

have participated with success at the intensive training session:

Application and technical training for following instruments:

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

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

Place of Training: **TECO – Germany**

Date: **November 18th, 2019**


Christian Hoetzi
General Manager



IVD

REF

A0230-010, A0230-040, A0230-100,

Intended Use

This product is used for the determination of prothrombin time (PT) in plasma according to Quick^{1,2}. The test is sensitive to the extrinsic pathway coagulation factors II, V, VII, X and fibrinogen and therefore used for oral anticoagulant therapy with Vitamin-K inhibitors like Warfarin or Marcumar and also for the quantitative determination of extrinsic coagulation factors. The PT measures the extrinsic clotting time (factor VII activation) of test plasma after the addition PT reagent.

Contents & Determinations

Product	TECLOT PT-S	TECLOT PT-S	TECLOT PT-S
Cat.No.	A0230-010	A0230-040	A0230-100
PT-S Reagent*	5x2 mL	10x4 mL	10x10 mL

Determinations

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

*contains an extract of Rabbit brain with buffer, stabilizers and Calcium chloride.

**Micro method (75µL in total)

Preparation

Reconstitute with high purity water with the volume stated on the vial label.

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

Let stand at room temperature with occasional swirling for at least 15 min. Then place reagent into instrument and let incubate for further 15 min. The reagent sediments and must be swirled before each testing. On Coatlon instruments, you can use a mixing bar for this.

Storage & Stability

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

	2-8 °C	20-25 °C	37°C
PT Reagent	5 days	36 hours	8 hours

Precautions

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

Specimen collection and storage⁴

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

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

Procedure**A. Automated Method: Coatlon A**

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

B. Manual Method: Coatlon M system

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

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

Expected Results

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

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

Standardisation and Calibration

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

INR results:

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

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

Activity % (Quick) result:

were calculated from a calibration curve, which is prepared from reference plasma (e.g. TECAL N) and dilutions in saline solution like 0.9% NaCl₂ or TECLOT IBS buffer. At least three or more calibration points are recommended. The calibration curve must be confirmed with control plasma in normal and abnormal range.

% of normal	100%*	50%	25%	12.5%**
diluted in saline	not dil.	1+1	1+3	1+7

*The median of at least 21 healthy individuals is defined as 100%.

**12.5% dilution may cause "+++" results in some cases, because the level of fibrinogen is too high diluted for optical detection.

Quality Control

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

Limitations

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

A. Specimen Collection. AVOID:

- Use only plastic tubes or siliconised glass.
- Delayed mixing of blood with anticoagulant.
- Contamination with tissue thromboplastin.
- Improper ratio of anticoagulant with blood.
- Hemolyzed, icteric or lipemic samples may interfere optical systems

B. Laboratory Techniques

- Perform tests at 37°C.
- Use only high purity water.
- Optimum pH is 7.0-7.5.
- ISI value is not constant within the first 30 min after reconstitution.
- Reagent sediments and must be swirled before each testing.

Performance Characteristics**Typical performance on instrument Coatlon M4**

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

Warranty

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

References

- Quick, A.J., The Hemorrhagic Diseases and the Physiology of Hemostasis. Charles C. Thomas: Springfield, IL. 1942.
- Quick, A.J., Hemorrhagic Diseases. Lea and Febiger: Philadelphia. 1957.
- Miale, J.B., Laboratory Medicine-Hematology, 4th Edition. C.V. Mosby: St. Louis. 1972.
- National Committee for Clinical Laboratory Standards: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays.
- Besselaar A M H P van den, Lewis SM, Mannucci P n Poller L. 1993. Status of present and candidate International Reference Preparations (IRP) of thromboplastin for prothrombin time. Thromb Hemostas 69: 85
- Besselaar A M H P van den. 1991. The significance of the International Normalized Ratio (INR) for oral anticoagulant therapy. H17CC 3; 146153.

Symbol keys

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





IVD

REF

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

Intended Use

The TEClot FIB is intended for the quantitative determination of fibrinogen in human plasma according to method developed by Clauss.¹ Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use². Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenemia (no detectable fibrinogen), hypofibrinogenemia (<1 mg/ml) and dysfibrinogenemia (abnormal fibrinogen molecule).

Contents & Preparation

Product	TEClot FIB Kit-10	TEClot FIB Kit-25	TEClot FIB	TEClot FIB
Cat.No.	A0501-010	A0501-025	A0511-020	A0511-050
Thrombin Reagent	5x2 mL	5x5 mL	10x2 mL	10x5 mL
IBS Buffer	1x125 mL	1x125 mL	-	-
TECal Normal	1x1 mL	1x1 mL	-	-
TEControl A	1x1 mL	1x1 mL	-	-

Determinations

Coatlon M*	400 Det.	1000 Det.	800 Det.	2000 Det.
Coatlon A4	200 Det.	500 Det.	400 Det.	1000 Det.
Coatlon A6	200 Det.	500 Det.	400 Det.	1000 Det.

*Micro method (75µl in total)

- Thrombin Reagent:
Contains bovine thrombin (~80NIH) with stabilizers
REF: A0501-010/A0511-020: Reconstitute with 2mL purified water
REF: A0501-025/A0511-050: Reconstitute with 5mL purified water
- IBS Buffer: Ready to use. Contains Imidazole buffered saline
- TECal Normal: Reconstitute with 1 mL purified water.
Contains citrated human plasma.
- TEControl A: Reconstitute with 1 mL purified water.
Contains citrated human plasma.



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

Storage & Stability

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

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

* Reagent must be protected from UV-light and evaporation

Precautions

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

Specimen collection and storage³

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

Procedure**A. Automated Method. Coatlon A**

Fibrinogen	A4	A6		A4	A6		A4	A6
PAT Patient	10µl	CP1	10µl	CP1	Incubation	0s	SENS	0
BUF IBS Buffer	90µl	P39	90µl	P79	Maxtime	120s	POINTS	4
CLR -	0µl	-	0µl	-	Unit	769	MIX	No
DP -	0µl	P00	0µl	P00	Method	Coag	Clean	1 3
R0 -	0µl	P00	0µl	P00	Math	log XY	Multi	1 1
R1 -	0µl	P00	0µl	P00	CT-Mech	Yes	S-Corr	0%
R2 Fibrinogen	50µl	P29	50µl	P49	Deadtime	3s	T-Corr	0%

B. Manual Method: Coatlon M**1. Preparation of Standard, Control and Patient Dilutions**

Standard Dilution	Plasma	IBS Buffer
1:5	200µL Standard	800µL
1:10	500µL 1:5 STD	500µL
1:20	500µL 1:10 STD	500µL
1:40	500µL 1:20 STD	500µL
Patient or Control	100µL Plasma	900µL

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

3. Add **25 µl Thrombin reagent** and simultaneously start test.

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

Calibration

TECal Normal or other commercially prepared plasma standard in which Fibrinogen has been determined should be used as reference (200-300mg/dL). Plot the clotting time obtained with each of the FIB standard dilutions on the y-axis against the concentration of FIB (mg/dL) on the x-axis using log-log graph paper. The line of best fit should be determined by linear regression analysis. The fibrinogen in plasma samples can be determined by interpolation from the calibration curve.

Expected Results

Typical normal results are 180-450 mg/dL^{4,5}. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

Quality Control

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

Limitations**A. Specimen Collection. AVOID:**

- Use only plastic tubes or siliconised glass.
- Delayed mixing of blood with anticoagulant.
- Contamination with tissue thromboplastin.
- Improper ratio of anticoagulant with blood.
- Hemolyzed, icteric or lipemic samples may interfere optical systems

B. Laboratory Techniques

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

Performance Characteristics

Precision:	CV% (within run)	CV% (inter-runs)
Normal control	< 5.0	< 5.0
Abnormal control	< 5.0	< 10.0

(Typical performance on instrument Coatlon M4)

Warranty

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

References

- Clauss, A., Gerinnungsphysiologische Schnellmethode zur bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
- Shaw, T.S., Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
- National Committee for the National Laboratory (NCCLS) Standards: Collection transport and preparation of blood specimens for coagulation testing and performance of coagulation assays. Document H21-A2, vol. 11, No. 23, 1991.
- Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37) : 37-48.
- Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6) : 196-201.

Symbols key:

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





IVD

REF

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

Verwendungszweck

TECLOT FIB wird zur quantitativen Bestimmung von Fibrinogen im menschlichen Plasma nach einer von Clauss¹ entwickelten Methode verwendet. Der Fibrinogenpegel kann auf Grund von Entzündungen, Schwangerschaft und dem Gebrauch von Ovulationshemmern ansteigen². Geringere Konzentrationen können bei verschiedenen Krankheiten wie Leberversagen und DIC auftreten. Angeborene Defizite beinhalten Afibrinogenämie (kein auffindbares Fibrinogen), Hypofibrinogenämie (<1 mg/ml) und Dysfibrinogenämie (abnormale Fibrinogenmoleküle).

Inhalte und Vorbereitungen

Produkt	TECLOT FIB Kit-10	TECLOT FIB Kit-25	TECLOT FIB A0511-020	TECLOT FIB A0511-050
Kat. Nr.	A0501-010	A0501-025	A0511-020	A0511-050
Thrombin Reagenz	5x2 mL	5x5 mL	10x2 mL	10x5 mL
IBS Puffer	1x125 mL	1x125 mL	-	-
TECal Normal	1x1 mL	1x1 mL	-	-
TEControl A	1x1 mL	1x1 mL	-	-

Bestimmungen

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

*Mikromethode (75µL insgesamt)

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

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

Lagerung und Stabilität

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

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

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

Vorsichtsmaßnahme

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

Probenentnahme und Lagerung³

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

Verfahren**A. Automatenmethode: Coatron A**

Fibrinogen	A4	A6		A4	A6		A4	A6
PAT Patient	10µl	CP1	10µl	CP1	Incubation	0s	SENS	0
BUF IBS Buffer	90µl	P39	90µl	P79	Maxtime	120s	POINTS	4
CLR -	0µl	-	0µl	-	Unit	769	MIX	No
DP -	0µl	P00	0µl	P00	Method	Coag	Clean	1 3
R0 -	0µl	P00	0µl	P00	Math	log XY	Multi	1 1
R1 -	0µl	P00	0µl	P00	CT-Mech	Yes	S-Corr	0%
R2 Fibrinogen	50µl	P29	50µl	P49	Deadtime	3s	T-Corr	0%

Erklärung der Symbole:

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

B. Manuelle Methode: Coatron M

- Vorbereitung von Standard-, Kontroll- und Patientenlösungen

Standardlösung	Plasma	IBS Puffer
1:5	200µL Standard	800µL
1:10	500µL 1:5 STD	500µL
1:20	500µL 1:10 STD	500µL
1:40	500µL 1:20 STD	500µL
Patient oder Kontrolle	100µL Plasma	900µL

- 50µL verdünntes Standard- oder Patientenplasma (1:10) in eine Küvette pipettieren. Bei 37°C für 1-2 Minuten erwärmen
 - 25µL Thrombinreagenz hinzufügen und gleichzeitig Test starten.
- Wenn Sie ein anderes Gerät verwenden, lesen Sie bitte für genauere Informationen die entsprechende Geräteanleitung.

Kalibrierung

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

Erwartete Ergebnisse

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

Qualitätskontrolle

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

Beschränkungen

A. Probenvorbereitung. Achten Sie auf:

- nur Plastikröhrchen oder silikonisiertes Glas verwenden
- verzögertes Mischen von Blut mit Antikoagulanzen vermeiden
- Kontamination mit Gewebethromboplastin vermeiden
- falsches Verhältnis von Antikoagulanzen und Blut vermeiden
- Hämolytische, lipämische oder ikterische Proben können optische Systeme stören

B. Labortechniken

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

Leistungsdaten

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

(Typische Leistung beim Gerät Coatron M4)

Garantie

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

Referenzen

- Clauss, A., Gerinnungsphysiologische Schnellmethode zur Bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
- Shaw, T.S., Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
- National Committee for the National Laboratory (NCCLS) Standards: Collection transport and preparation of blood specimens for coagulation testing and performance of coagulation assays. Document H21-A2, vol. 11, No. 23, 1991.
- Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37): 37-48.
- Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6): 196-201.



**Revisions-Übersicht:**

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



IVD

REF

A0590-125

Intended Use

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

Contents & Determinations

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

Preparation

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

Storage and Stability

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

Precautions

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

Warranty

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

Symbols key:

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





Verwendungszweck

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

Inhalte und Bestimmungen

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

Vorbereitung

IBS: pH 7.3 - 7.4, flüssig
Gebrauchsfertig

Lagerung und Stabilität

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

Vorsichtsmaßnahmen

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

Garantie

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

Erklärung der Symbole:

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





IVD

REF

P6001-010

Intended Use

Use as a normal control for following coagulation tests:

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

Contents

10 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation

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

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

Storage & Stability

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

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

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

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

Precautions

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

Expected Results

Refer to "Certificate of Analysis".

Warranty

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

Symbols key:

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





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 Veräußerlichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

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





IVD

REF

P6101-010

Intended Use

Use as an abnormal control for following coagulation tests:

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

Contents

10 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation

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

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

Storage & Stability

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

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Symbols key:

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Store at 2-8°C	EU conformity	Manufacturer	Lot. Number	Authorized Representative





IVD

REF

P6101-010

Verwendungszweck

Als abnormale Kontrolle für folgende Gerinnungstests verwenden:

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

Inhalt

10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung

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

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Lagerung und Stabilität

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

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Erwartete Ergebnisse

Lesen Sie das Analysenzertifikat

Garantie

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Erklärung der Symbole:

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

