Atlas Medical

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH
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Agent: San Medico
Republic of Moldova, city Chisina
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Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Maldova

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
Quality Diagnostic Products

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

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**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

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

GMED N° 36655–2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

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
FF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical
Head office: Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow, Germany.
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
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Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (Annexl) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  Certificate N^{0}.: 36655 rev 1
  Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March.2021	09.03.2021		

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card,stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

Atlas Medical
Quality Diagnostic Products

ASO LATEX KIT

IVD For in -*vitro* diagnostic and professional use only

Store at 2-8°C. CE

INTENDED USE

ATLAS ASO latex Test is used for the qualitative and semi-quantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTRODUCTION

The group A ß-hemolytic streptococci produce various toxins that can act as antigens. One of these exotoxins streptolysin-O, was discovered by Todd in 1932.

A person infected with group A hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin-O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the hemolytic streptococcal.

The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pre-titrated and reduced streptolysin-O. However, the antigen-antibody reaction occurs independently of the hemolytic activity of streptolysin-O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin-O by agglutination of latex particles on slide.

PRINCIPLE

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level is present in the test specimen.

MATERIALS

MATERIALS PROVIDED

- ASO Latex Reagent: Latex particles coated with streptolysin O, pH, 8,2. Preservative**.**
- ASO Positive Control (Red cap): Human serum with an ASO concentration > 200 IU/mL.Preservative.
- ASO Negative Control (Blue cap) Animal serum. Preservative
- Glass Slide.
- Stirring Sticks.

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

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.
- Glycine Buffer 20x (1000 mmol/l): add one part to nineteen parts of distilled water before use.

Packaging contents

REF **8.00.02.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- 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.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

The ASO Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- **DO NOT FREEZE.**
- The ASO Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagents deterioration: Presence of particles and turbidity.

SAMPLES

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- **DO NOT USE PLASMA.**

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (40 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

1. Make serial two-fold dilutions of the sample in 9 g/L saline solution.

2. Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative Controls should be included in each test batch.
- Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

CALCULATIONS

The approximate ASO concentration in the patient sample is calculated as follows:

200 x ASO Titer = IU/mL

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

200 (±50) IU/ml.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

SENSITIVITY

98%.

SPECIFICITY

97%.

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10 g/L)
- Bilirubin(20 mg/dL)
- Lipids (10 g/L)
- Rheumatoid factors (300 IU/mL)
- Other substances may interfere.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the ASO Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative ASO concentration; therefore, screening reactions should not be graded.
- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 2 years may cause false negative results. A single ASO determination does not produce much information about the actual state of the disease.
- Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

1. Haffejee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
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3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279.
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5. Picard B et al. La Presse Medicale 1983; 23: 2-6.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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PPI2325A01
Rev A (05.01.2023)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	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
CONTROL +	Positive control	CONTROL -	Negative control

RF LATEX KIT

IVD For In-*Vitro* diagnostic and professional use only

Store at 2-8°C CE

INTENDED USE

Atlas RF latex test for the qualitative and semi-quantitative measurement of RF in human serum.

INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.

One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz. The major advantage of this method is rapid performance (2-minutes reaction time) and lack of heterophile antibody interference.

PRINCIPLE

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

MATERIALS

MATERIALS PR0VIDED

- RF Latex Reagent: Latex particles coated with human gamma-globulin, pH, 8,2. Preservative.
- RF Positive Control Serum (Red Cap): Human serum with a RF concentration > 30 IU/Ml. Preservative.
- *RF Negative Control (Blue Cap): Non-reactive buffer containing BSA and 0.1% sodium azide.
- *Glycine Buffer 20X (1000 mmol/L) (Optional): add one part to nineteen parts of distilled water before use.
- *Black glass Slide
- Stirring sticks

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

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Pipettes 50 µL
- *9 g/L saline.

Packaging contents

REF **8.00.04.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

PRECAUTIONS

- *For *in vitro* diagnostic and professional use only. The test is not for near-patient or self-testing.
- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- 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.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent *(35µL ±5µL). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- *Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.
- *Wash the area of contact with water immediately if contact occurs.
- *Do not drink or ingest the reagent.
- *Do not use the reagent if the label is missing, damaged, or unclear.
- *Do not use white or transparent glass slides during testing.
- *Perform the test in a well-lit area with good visibility.
- *Close the vial after each test.
- *Failure in following the instructions may give incorrect results or face safety hazards.
- *Handle the used disinfectant with care.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

REAGENT PREPARATION:

- The RF Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- Do not freeze.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- The RF latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use PLASMA.

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. *Swirl the reagent gently before use and add one drop (35 µL ±5µL) next to the sample to be tested.
4. *Close the vial tightly after use.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
6. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

***Semi-quantitative method**

Prepare serial two-fold dilutions of the sample in 9 g/L saline/glycine buffer (1X):

1. Allow the reagents and samples to reach room temperature.
2. Add (40 µL) of 9 g/L saline/glycine buffer (1X) into 6 circles of the black glass slide.
3. Add (40 µL) of the serum sample to the first circle.
4. Mix well using the pipette and then transfer (40 µL) from the first circle to the second circle, repeat until finishing the six circles.
5. Swirl the reagent vial.
6. Add one drop of RF reagent (35µL ±5µL) next to the samples in each circle.
7. Close the reagent vial.
8. Mix the drops with a stirrer, spreading them over the entire surface of the circle.
9. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a RF concentration equal or greater than 8 IU/mL (Note 1).

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate RF concentration in the patient sample is calculated as follows:

8 x RF Titer = IU/mL

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

8 (6-16) IU/ml, under the described assay conditions.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

DIAGNOSTIC SENSITIVITY

100%.

DIAGNOSTIC SPECIFICITY

100%.

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

***PRECISION**

100%.

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10g/L)
- Bilirubin (20mg/dl)
- Lipids (10g/L)

Other substances may interfere.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the RF Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.
- Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome.
- Certain patients with rheumatoid arthritis will not have the RF present in their serum.
- The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
- Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

REFERENCE VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

NOTES

1. Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

REFERENCES

1. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1 – 21.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 –534.
4. Adalbert F. Schubart et al. The New England Journal of Medicine 1959; 261: 363 – 368.
5. Charles M. Plotz 1956; American Journal of Medicine; 21:893 – 896.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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PPI2326A01
Rev B (30.03.2024)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	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
CONTROL +	Positive control	CONTROL -	Negative control

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

CRP LATEX KIT

IVD For *in vitro* diagnostic and professional use only

2°C 8°C Store at 2-8°C. CE

INTENDED USE

Atlas CRP Latex kit is a manual slide latex agglutination test for the qualitative and semi-quantitative detection of C-reactive protein (CRP) in human serum to aid in the diagnosis of individuals with suspected inflammation.

INTRODUCTION

C-reactive protein (CRP) is an evolutionarily conserved constitutive protein produced primarily by hepatocytes in minute amounts. At baseline levels, CRP mediates important biological functions. Its clinical significance as a component of the acute phase response emerged upon linking elevated blood levels of CRP to trauma, infection and inflammatory non-infectious disorders including autoimmune diseases. Its concentration can increase up to 1000-fold in severe inflammatory insults. CRP quickly rises in blood upon the onset of an acute stimulus (within 6 hours), and may double every 8 hours reaching a peak at 50 hours. Likewise, blood CRP rapidly drops upon cessation of the stimulus in an exponential manner. Although non-discriminatory of the root cause, elevated serum CRP has been established as an important marker of inflammation.

PRINCIPLE

The C-Reactive Protein test is based on the principle of the latex agglutination. When latex particles complexed with human anti-CRP are mixed with a patient's serum containing C- reactive protein, a visible agglutination reaction will take place within 2 minutes.

KIT COMPONENTS

Materials Provided

- **CRP Latex Reagent:** Latex particles coated with goat IgG anti-human CRP (approximately 1 %), pH 7.4. **MIX WELL BEFORE USE.**
- **CRP Positive Control (Red Cap):** Diluted human serum with CRP concentration > 20mg/L.
- **CRP Negative Control (Blue Cap):** Non-reactive buffer containing BSA and 0.1% sodium azide.
- **Glycine Buffer 20X (1000 mmol/L) (Optional):** add one part to nineteen parts of distilled water before use.
- **Black Glass Slide.**
- **Stirring Sticks.**
- **Package insert.**

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

Materials Required But Not Provided

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Calibrated 50 µL micro-pipette.
- 9 g/L saline.

Packaging Contents

REF **8.00.00.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

REAGENT STORAGE AND STABILITY

- Reagents are stable until specified expiry date on vial label when stored refrigerated (2 - 8°C).
- **DO NOT FREEZE.**
- The CRP latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in a vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagent deterioration: Presence of particles and turbidity.

PRECAUTIONS AND WARNINGS

- For *in vitro* diagnostic and professional use only. The test is not for near-patient or self-testing.
- All reagents contain 0.1% (w/v) Sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- This kit is NOT to be used in CRP-guided therapy.
- Components containing human serum were tested for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) as required by FDA; and found to be negative. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (35 µL ±5µL). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- 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
- Wash the area of contact with water immediately if contact occurs.
- failure in following the instructions may give incorrect results or incur safety hazards
- Handle the used disinfectant with care.
- Close the vial after each test.
- Perform the test in a well-lit area with good visibility.
- Do not use white or transparent glass slides during testing.
- Do not touch, drink, or ingest the reagent.
- Certain nutritional supplements may effect on CRP levels.
- 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

- Use fresh serum collected by centrifuging clotted blood.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- **Do not use plasma**.

SPECIMEN STORAGE AND STABILITY

If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C. Frozen samples should be completely thawed and brought to room temperature before testing. Avoid repeated freezing and thawing of the samples.

REAGENT PREPARATION

The CRP Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

PROCEDURE

NOTE: The latex and sample volumes are very critical for correct test performance. Please adhere to the volumes stipulated in this package insert.

QUALITATIVE TEST:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop (40 µL ±5µL) of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the CRP latex reagent gently and add one drop (35 µL

±5µL) next to the samples and controls to be tested.
4. Close the reagent vial tightly.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample and each control.
6. Place the slide on a mechanical rotator at 80-100 r.p.m. for **2 minutes**. False positive results could be obtained if the test is read later than two minutes.

B. SEMI-QUANTITATIVE TEST:

Prepare serial two-fold dilutions of the sample in 9 g/L saline/glycine buffer (1X):

1. Allow the reagents and samples to reach room temperature.
2. Add (40 µL) of 9 g/L saline/glycine buffer (1X) into 6 circles of the black glass slide.
3. Add (40 µL) of the serum sample to the first circle.
4. Mix well using the pipette and then transfer (40 µL) from the first circle to the second circle, repeat until finishing the six circles.
5. Swirl the reagent vial.
6. Add one drop of CRP reagent (35µL ±5µL) next to the samples in each circle.
7. Close the reagent vial.
8. Mix the drops with a stirrer, spreading them over the entire surface of the circle.
9. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes.

CALCULATIONS

The approximate CRP concentration in the patient sample is calculated as follows:

Sensitivity x CRP Titer = mg/L

(Sensitivity indicated on the label of the latex vial)

INTERPRETATION OF THE RESULT

Examine macroscopically the presence or absence of visible agglutination immediately after stopping the rotator.

The presence of agglutination indicates a CRP concentration equal or greater than the reagent sensitivity (mg/L CRP) (indicated on the label of the latex vial).

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Each laboratory should establish its own reference range.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the kit, as well as providing a comparative pattern for better result interpretation.
- Any result that differs from the negative control result is considered positive.

LIMITATIONS OF THE TEST

- Reaction time is critical. If reaction time exceeds two (2) minutes, the reaction mixture may dry causing particles, which can be mistaken for false positive results.
- Freezing the CRP Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, reactions should not be graded.
- A false negative can be attributed to a prozone phenomenon (antigen excess). It is recommended, therefore, to check all suspected negative sera by retesting with a 1:10 dilution in 9 g/L saline/glycine buffer (1X).

PERFORMANCE CHARACTERISTICS

- **Sensitivity:** 6 mg/L.
- **Prozone effect:** No prozone effect was detected up to 1600 mg/L.
- **Diagnostic sensitivity: 100 %** in comparison with a commercial latex kit.
- **Diagnostic specificity: 100 %** in comparison with a commercial latex kit.
- **Precision : 100%**
- **Interferences:**

  No interference was observed with the following substances at the concentrations indicated:
  - Hemoglobin (<15 g/dl)
  - Bilirubin (<20 mg/dl)
  - Lipids (<13 g/dL)
  - Other substances interfere, such as RF (>75IU/ml).

NOTES

- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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Website: www.atlas-medical.com

PPI2327A01
Rev B (10.02.2024)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	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
CONTROL+	Positive control	CONTROL-	Negative control

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

Distribution Authorisation Letter

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

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

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

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

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

Products:

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

all instruments with complete accessory, consumables and spare parts

- Hemostasis Reagents Complete product line

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

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl
General Management

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

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

Certificate of Approval

This is to certify that the Management System of:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00038268

The scope of this approval is applicable to:

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

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited

UKAS MANAGEMENT SYSTEMS 0001

TECO

CE

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

Doc#200/12-2023

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

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

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

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

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

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

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

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

Ort und Datum der Unterzeichnung: Neufahrn, 2023-12-20
Place and date of issue:

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC

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Doc#200/12-2023

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

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

Pos.	Article No	Tradename	Unit	Generic Device Term	EMDN / GMDN Code 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-APTTS-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

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

Quality Management EN ISO 13485 DEKRA Certified

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CERTIFICATE

for: **Mr. Vitalie Goreacii**

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

have participated with success at the intensive training session:

Application and technical training for following instruments:

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

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

Place of Training: TECO – Germany

Date: November 18th, 2019

Christian Hoetzl
General Manager

TEClot PT-S

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

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

Contents & Determinations

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

Determinations

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

*contains an extract of Rabbit brain with buffer, stabilizers and Calcium chloride.
**Micro method (75µL in total)

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

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

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

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

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

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

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

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

Procedure
A. Automated Method: Coatron A

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

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

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

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

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

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

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

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

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

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

Activity % (Quick) result:
were calcaluted from a calibration curve, which is prepared from reference plasma (e.g. TECAL N) and dilutions in saline solution like 0.9% $NaCl_2$ or TECLOT IBS buffer. At least three or more calibration points are recommended. The calibration curve must be confirmed with control plasma in normal and abnormal range.

% of normal	100%*	50%	25%	12,5%**
diluted in saline	not dil.	1+1	1+3	1+7

* The median of at least 21 healthy individuals is defined as 100%.[5]
**12.5% dilution may cause "+++" results in same cases, because the level of fibrinogen is too high diluted for optical detection.

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

Limitations
Great care must be taken to minimize variations which may occur by seemingly insignificant factors.
A. Specimen Collection. AVOID:
1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfere optical systems

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

Performance Characteristics
Typical performance on instrument Coatron M4

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

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

References

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5. Besselaar A M H P van den, Lewis SM, Mannucci P n Poller L. 1993. Status of present and candidate International Reference Preparations (IRP) of thromboplastin for prothrombin time. Thromb Hemostas 69; 85
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Symbol keys

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

TEClot FIB

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

Intended Use

The TEClot FIB is intended for the quantitative determination of fibrinogen in human plasma according to method developed by Clauss.[1] Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use[2]. Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenaemia (no detectable fibrinogen), hypofibrinogenaemia (<1 mg/ml) and dysfibrinogenaemia (abnormal fibrinogen molecule).

Contents & Preparation

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

Determinations

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

*Micro method (75µL in total)

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

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

Storage & Stability

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

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

* Reagent must be protected from UV-light and evaporation

Precautions

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

Specimen collection and storage[3]

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

Procedure

A. Automated Method. Coatron A

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

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

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

B. Manual Method: Coatron M

1. Preparation of Standard, Control and Patient Dilutions

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

2. Pipette **50 µl diluted standard or patient plasma** (1:10) into a test cuvette. Prewarm at 37°C for 1-2 minutes.
3. Add **25 µl Thrombin reagent** and simultaneously start test.

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

Calibration

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

Expected Results

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

Quality Control

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

Limitations

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

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

Performance Characteristics

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

(Typical performance on instrument Coatron M4)

Warranty

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

References

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

Symbols key:

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

TEClot FIB

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

Verwendungszweck

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

Inhalte und Vorbereitungen

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

Bestimmungen

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

*Mikromethode (75µL insgesamt)

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

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

Lagerung und Stabilität

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

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

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

Vorsichtsmaßnahme

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

Probenentnahme und Lagerung [3]

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

Verfahren

A. Automatenmethode: Coatron A

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

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

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

B. Manuelle Methode: Coatron M

1. Vorbereitung von Standard-, Kontroll- und Patientenlösungen

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

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

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

Kalibrierung

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

Erwartete Ergebnisse

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

Qualitätskontrolle

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

Beschränkungen

A. Probenvorbereitung. Achten Sie auf:
1. nur Plastikröhrchen oder silikonisiertes Glas verwenden
2. verzögertes Mischen von Blut mit Antikoagulanz vermeiden
3. Kontaminierung mit Gewebethromboplastin vermeiden
4. falsches Verhältnis von Antikoagulanz und Blut vermeiden
5. Hämolytische,lipämische oder ikterische Proben können optische Systeme stören

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

Leistungsdaten

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

(Typische Leistung beim Gerät Coatron M4)

Garantie

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

Referenzen

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

Erklärung der Symbole:

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

Revisions-Übersicht:

Rev.	am	Änderung durch	Gültig für	Freigabe am	Freigabe durch
1	5.4.11	WG	Technoclone FIB		
	Beschreibung:	New box insert for Technoclone FIB.			
2	21.12.11	CB	Technoclone FIB	21.12.11	CH
	Beschreibung:	Neue Stabilitätsangaben. Die Vorgaben wurden dem Technoclone Stability Test Report „TC6E0C.01“ vom 5.5.2010 entnommen.			
3	11.11.13	CB	Technoclone FIB		
	Beschreibung:	- Protokoll für A4+A6 - 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.			

IBS Buffer

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

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

Contents & Determinations

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

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

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

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

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

Symbols key:

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

IBS Buffer

CE IVD REF *A0590-125*

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

Inhalte und Bestimmungen

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

Vorbereitung
IBS: pH 7.3 - 7.4, flüssig
Gebrauchsfertig

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

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

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

Erklärung der Symbole:

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

TEControl N

CE IVD REF **P6001-010**

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

PT, APTT, Thrombintime, Fibrinogen, Antithrombin and D-Dimer

Contents
10 x 1mL freeze dried citrate-anticoagulated human plasma

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

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

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

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

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

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

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

Expected Results
Refer to "Certificate of Analysis".

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

Symbols key:

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

TEControl N

CE | IVD | REF | P6001-010

Verwendungszweck
Als normale Kontrolle für folgende Gerinnungstests verwenden:

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

Inhalt
10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

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

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

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

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

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

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

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

Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

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

Erklärung der Symbole:

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

TEControl A

CE IVD REF **P6101-010**

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

PT, APTT, Thrombintime, Fibrinogen,
Antithrombin and D-Dimer

Contents
10 x 1mL freeze dried citrate-anticoagulated human plasma

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

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

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

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

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

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

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

Expected Results
Refer to "Certificate of Analysis".

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

Symbols key:

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

TEControl A

CE IVD REF P6101-010

Verwendungszweck
Als abnormale Kontrolle für folgende Gerinnungstests verwenden:

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

Inhalt
10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

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

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

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

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

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

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

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

Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

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

Erklärung der Symbole:

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