



## STATEMENT

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

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

Date: January 3, 2023

Signature:

A handwritten signature in black ink, appearing to read "Xie", is written over a horizontal line.

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



# EC Certificate

Full Quality Assurance System

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

**No. V1 104507 0003 Rev. 06**

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

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

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1\\_104507\\_0003\\_Rev.06](http://www.tuvsud.com/ps-cert?q=cert:V1_104507_0003_Rev.06)

**Report no.:** SH22743EXT01

**Valid from:** 2022-05-04

**Valid until:** 2025-05-26

**Date,** 2022-05-04

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

Full Quality Assurance System

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

**No. V1 104507 0003 Rev. 06**

## Model(s):

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



# EC Certificate

Full Quality Assurance System

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

## No. V1 104507 0003 Rev. 06

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

### Facility(ies):

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

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

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

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





Product Service

# Certificate

No. Q5 104507 0001 Rev. 03

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

**Certification Mark:**



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

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

**Report No.:** SH22743A01

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

**Date,** 2022-09-15

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 104507 0001 Rev. 03

**Applied Standard(s):**

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

**Facility(ies):**

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

Address holder for registration only

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

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

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

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

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

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

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

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

## Declaration of Conformity

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

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

*Mission*<sup>®</sup> Urinalysis Reagent Strips (U031-XX1)

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

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

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

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

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



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



# Declaration of Conformity

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

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

Device Name	REF Number	Model Number
Mission® Liquid Urine Control	U021-011	n/a
SPINREACT Liquid Urine Control	U021-013A	n/a
Insight® Liquid Urine Control	U021-015	n/a
Mission® Liquid Diptube Urine Control	U021-071	n/a
Insight® Liquid Diptube Urine Control	U021-075	n/a

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

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

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

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

Signed this 22 day of October, 2021  
in San Diego, CA, USA



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





**Mission® Urinalysis Reagent Strips Visual Reading**

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)			Level 1 (14C and 13CE) (Lot#17110079)			Level 2 (14C and 13CE) (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Leukocytes (LEU)	Negative	Negative	-	15-500 Leu/µL	15-500 Leu/µL	+/- - 3+	Negative	Negative	-	15-500 Leu/µL	15-500 Leu/µL	+/- - 3+
Nitrite (NIT)	Negative	Negative	-	Positive	Positive	+	Negative	Negative	-	Positive	Positive	+
Urobilinogen (URO)	0.2 - 1mg/dL	3.5 - 17µmol/L	-- ±	2 - 12 mg/dL	35 - 200µmol/L	1+ - 4+	0.2 - 1 mg/dL	3.5 - 17µmol/L	-- ±	2 - 12 mg/dL	35 - 200µmol/L	1+ - 4+
Protein (PRO)	Negative	Negative	-	30 - 200mg/dL	0.3 - 20.0g/L	1+ - 4+	Negative	Negative	-	30 - 200mg/dL	0.3 - 20.0g/L	1+ - 4+
pH	5.0 - 7.0	5.0 - 7.0	5.0 - 7.0	6.5 - 9.0	6.5 - 9.0	6.5 - 9.0	5.0 - 7.0	5.0 - 7.0	5.0 - 7.0	6.5 - 9.0	6.5 - 9.0	6.5 - 9.0
Blood (BLO)	Negative	Negative	-	25 - 200 Ery/µL	25 - 200 Ery/µL	1+ - 3+	Negative	Negative	-	25 - 200 Ery/µL	25 - 200 Ery/µL	1+ - 3+
Specific Gravity (SG)	1.015 - 1.030	1.015 - 1.030	1.015 - 1.030	1.005 - 1.025	1.005 - 1.025	1.005 - 1.025	1.015 - 1.030	1.015 - 1.030	1.015 - 1.030	1.005 - 1.025	1.005 - 1.025	1.005 - 1.025
Ketone (KET)	Negative	Negative	-	5 - 160mg/dL	0.5-16.0mmol/L	± - 4+	Negative	Negative	-	5-160mg/dL	0.5-16.0mmol/L	± - 4+
Bilirubin (BIL)	Negative	Negative	-	1 - 4 mg/dL	17 - 70µmol/L	1+ - 3+	Negative	Negative	-	1 - 6 mg/dL	17 - 100µmol/L	1+ - 3+
Glucose (GLU)	Negative	Negative	-	100-1000mg/dL	5 - 60mmol/L	± - 3+	Negative	Negative	-	100-1000mg/dL	5 - 60mmol/L	1+ - 4+
Ascorbic Acid (ASC)	Negative	Negative	-	Negative	Negative	-	Negative	Negative	-	Negative	Negative	-
Microalbumin (ALB)	10 - 30mg/L	10 - 30mg/L	10 - 30mg/L	80 - 150mg/L	80 - 150mg/L	80 - 150mg/L	10 - 30mg/L	10 - 30mg/L	10 - 30mg/L	80 - 150mg/L	80 - 150mg/L	80 - 150mg/L
Creatinine (CRE)	10 - 100mg/dL	0.9-8.8mmol/L	10 - 100mg/dL	100 - 300mg/dL	8.8-26.5mmol/L	100 - 300mg/dL	10 - 100mg/dL	0.9-8.8mmol/L	10 - 100mg/dL	100 - 300mg/dL	8.8-26.5mmol/L	100 - 300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	NA	NA	NA	NA	NA	NA
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Calcium (CA)	4 - 10mg/dL	1.0-2.5mmol/L	4 - 10mg/dL	20 - 40mg/dL	5.0-10mmol/L	20 - 40mg/dL	4 - 10mg/dL	1.0-2.5mmol/L	4 - 10mg/dL	20 - 40mg/dL	5.0-10mmol/L	20 - 40mg/dL

**Mission® Urinalysis Reagent Strips Analyzer Reading with Mission® U120/U500/U120 Ultra\***

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)			Level 1 (14C and 13CE) (Lot#17110079)			Level 2 (14C and 13CE) (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Leukocytes (LEU)	Negative	Negative	-	15-500 Leu/µL	15-500 Leu/µL	+/- - 3+	Negative	Negative	-	15-500 Leu/µL	15-500 Leu/µL	+/- - 3+
Nitrite (NIT)	Negative	Negative	-	Positive	Positive	+	Negative	Negative	-	Positive	Positive	+
Urobilinogen (URO)	0.2 - 1mg/dL	3.5 - 17µmol/L	-- ±	2 - 8 mg/dL	35 - 140µmol/L	1+ - 3+	0.2 - 1 mg/dL	3.5 - 17µmol/L	-- ±	2 - 8 mg/dL	35 - 140µmol/L	1+ - 3+
Protein (PRO)	Negative	Negative	-	30 - 300mg/dL	0.3 - 3.0g/L	1+ - 3+	Negative	Negative	-	30 - 300mg/dL	0.3 - 3.0g/L	1+ - 3+
pH	5.0 - 7.0	5.0 - 7.0	5.0 - 7.0	6.5 - 9.0	6.5 - 9.0	6.5 - 9.0	5.0 - 7.0	5.0 - 7.0	5.0 - 7.0	6.5 - 9.0	6.5 - 9.0	6.5 - 9.0
Blood (BLO)	Negative	Negative	-	25 - 200 Ery/µL	25 - 200 Ery/µL	1+ - 3+	Negative	Negative	-	25 - 200 Ery/µL	25 - 200 Ery/µL	1+ - 3+
Specific Gravity (SG)	1.015 - 1.030	1.015 - 1.030	1.015 - 1.030	1.005 - 1.025	1.005 - 1.025	1.005 - 1.025	1.015 - 1.030	1.015 - 1.030	1.015 - 1.030	1.005 - 1.025	1.005 - 1.025	1.005 - 1.025
Ketone (KET)	Negative	Negative	-	5 - 80mg/dL	0.5-8.0mmol/L	± - 3+	Negative	Negative	-	5-80mg/dL	0.5-8.0mmol/L	± - 3+
Bilirubin (BIL)	Negative	Negative	-	1 - 4 mg/dL	17 - 70µmol/L	1+ - 3+	Negative	Negative	-	1 - 6 mg/dL	17 - 100µmol/L	1+ - 3+
Glucose (GLU)	Negative	Negative	-	100-1000mg/dL	5 - 60mmol/L	± - 3+	Negative	Negative	-	100-1000mg/dL	5 - 60mmol/L	1+ - 4+
Ascorbic Acid (ASC)	Negative	Negative	-	Negative	Negative	-	Negative	Negative	-	Negative	Negative	-
Microalbumin (ALB)	10 - 30mg/L	10 - 30mg/L	10 - 30mg/L	80 - 150mg/L	80 - 150mg/L	80 - 150mg/L	10 - 30mg/L	10 - 30mg/L	10 - 30mg/L	80 - 150mg/L	80 - 150mg/L	80 - 150mg/L
Creatinine (CRE)	10 - 100mg/dL	0.9-8.8mmol/L	10 - 100mg/dL	100 - 300mg/dL	8.8-26.5mmol/L	100 - 300mg/dL	10 - 100mg/dL	0.9-8.8mmol/L	10 - 100mg/dL	100 - 300mg/dL	8.8-26.5mmol/L	100 - 300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	NA	NA	NA	NA	NA	NA
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Calcium (CA)	4 - 10mg/dL	1.0-2.5mmol/L	4 - 10mg/dL	20 - 40mg/dL	5.0-10mmol/L	20 - 40mg/dL	4 - 10mg/dL	1.0-2.5mmol/L	4 - 10mg/dL	20 - 40mg/dL	5.0-10mmol/L	20 - 40mg/dL

**Mission® Expert Urinalysis Reagent Strips Visual Reading**

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Ascorbic Acid (ASC)	Negative	Negative	-	Negative	Negative	-
Blood (ERY, Hb)	Negative	Negative	-	Ca 25 - Ca 250 Ery/µl	Ca 25 - Ca 250 Ery/µl	2+ - 4+
Bilirubin (BIL)	Negative	Negative	-	1 - 6 mg/dL	17 - 100µmol/L	1+ - 3+
Urobilinogen (URO)	0.2 mg/dL	3.5 µmol/L	-	4 - 12 mg/dL	70 - 200 µmol/L	2+ - 4+
Ketone Bodies (KET)	Negative	Negative	-	10 - 150 mg/dL	1.0 - 15.0 mmol/L	1+ - 3+
Glucose (GLU)	Negative	Negative	-	100 - 1000 mg/dL	5.5 - 56 mmol/L	2+ - 4+
Protein (PRO)	Negative	Negative	-	30 - 500 mg/dL	0.3 - 5.0 g/L	1+ - 3+
Nitrite (NIT)	Negative	Negative	-	Positive	Positive	+
Leukocytes (LEU)	Negative	Negative	-	ca 10-25 - ca. 500 Leu/µl	ca 10-25 - ca. 500 Leu/µl	1+ - 3+
pH	5.0 - 7.0	5.0 - 7.0	5.0 - 7.0	7.0 - 9.0	7.0 - 9.0	7.0 - 9.0
Specific Gravity (SG)	1.015 - 1.030	1.015 - 1.030	1.015 - 1.030	1.005 - 1.025	1.005 - 1.025	1.005 - 1.025
Microalbumin (ALB)	10 - 30 mg/L	10 - 30mg/L	10 - 30 mg/L	80 - 150 mg/L	80 - 150 mg/L	80 - 150 mg/L
Creatinine (CRE)	10 - 100 mg/dL	0.9 - 8.8 mmol/L	10 - 100 mg/dL	100 - 300 mg/dL	8.8 - 26.5 mmol/L	100 - 300 mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal

**Mission® Expert Urinalysis Reagent Strips Analyzer Reading with Mission® Expert U120/U500\***

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Ascorbic Acid (ASC)	Negative	Negative	-	Negative	Negative	-
Blood (ERY, Hb)	Negative	Negative	-	25 - 250 Ery/µl	25 - 250 Ery/µl	2+ - 5+
Bilirubin (BIL)	Negative	Negative	-	1 - 6 mg/dL	17 - 100 µmol/L	1+ - 3+
Urobilinogen (URO)	0.2 mg/dL	3.5 µmol/L	-	4 - 12 mg/dL	70 - 200 µmol/L	2+ - 4+
Ketone Bodies (KET)	Negative	Negative	-	15 - 150 mg/dL	1.5 - 15.0 mmol/L	2+ - 4+
Glucose (GLU)	Negative	Negative	-	100 - 1000 mg/dL	5.5 - 56 mmol/L	2+ - 4+
Protein (PRO)	Negative	Negative	-	25 - 500 mg/dL	0.25 - 5.0 g/L	1+ - 4+
Nitrite (NIT)	Negative	Negative	-	Positive	Positive	+
Leukocytes (LEU)	Negative	Negative	-	25 - 500 Leu/µl	25 - 500 Leu/µl	1+ - 3+
pH	5.0 - 7.0	5.0 - 7.0	5.0 - 7.0	6.5 - 9.0	6.5 - 9.0	6.5 - 9.0
Specific Gravity (SG)	1.015 - 1.030	1.015 - 1.030	1.015 - 1.030	1.005 - 1.025	1.005 - 1.025	1.005 - 1.025
Microalbumin (ALB)	10 - 30 mg/L	10 - 30 mg/L	10 - 30 mg/L	80 - 150 mg/L	80 - 150 mg/L	80 - 150mg/L
Creatinine (CRE)	10 - 100 mg/dL	0.9 - 8.8 mmol/L	10 - 100 mg/dL	100 - 300 mg/dL	8.8 - 26.5 mmol/L	100 - 300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal

\*The U120 QC set-up screen recognizes only arbitrary values (LCD0187-05)



For validating visual and analyzer reading of urinalysis.  
For in vitro diagnostic use only.

### INTENDED USE

The Liquid Urine Control is intended for use in validating the visual and analyzer reading of urinalysis. The results should be compared to the expected results listed below to ensure the consistent performance of Mission® and Mission® Expert Urinalysis Reagent Strips and Urine Analyzers. The Liquid Urine Control is available in two levels and is ready to use for monitoring routine urinalysis.

### PRECAUTIONS

- For in vitro diagnostic use only. Do not use after the expiration date.
- All materials should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Discard if there is excessive turbidity or evidence of microbial contamination.
- The used materials should be discarded according to local regulations after testing.
- This product is not intended for use as a standard.
- The use of quality control materials is an important part of good laboratory practices. Quality control materials are an objective method of assessing techniques or practices in use.

### REAGENTS

The product is a liquid stable control prepared from simulated human urine with added chemicals, constituents of animal origin, preservatives and stabilizers. The control does not include human resource materials. Various pure chemicals are used to adjust each analyte level.

### STORAGE AND STABILITY

- Store and ship at 2-8°C (36-46°F). Do not freeze.
- Controls are stable until the expiration date printed on the bottle label when stored at 2-8°C (36-46°F).
- All analytes are stable for 30 days at 15-30°C (59-86°F) or until the expiration date at 2-8°C (36-46°F) once opened and stored with the cap on tightly.

### MATERIALS

#### Materials Provided

- Package Insert

#### Materials Required But Not Provided

- Timer

- Liquid Urine Control Level 1 and/or Level 2
- Strips

### DIRECTIONS FOR USE

Allow all test materials to reach room temperature (15-30°C or 59-86°F) prior to testing.

1. Invert the urine control bottle 3 times to ensure reproducible results, then remove the cap. While holding the urinalysis reagent strip, invert the urine control bottle and gently squeeze the urine control bottle to dispense the urine control. Ensure each reagent area on urinalysis reagent strip is completely saturated with urine control. See illustration 1 below.

#### Note:

- Do not touch the tip of the urine control bottle to the reagent areas on the urinalysis reagent strip to avoid contamination.
- Dispense the remaining hanging drop of urine control before turning the urine control bottle upright.

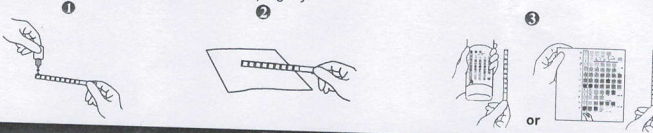
2. Hold the strip in a horizontal position to avoid contaminating the unused control with reagents from the urinalysis reagent strip. Dispose of the hanging drop of urine control to avoid contaminating the unused control with reagents from the urinalysis reagent strip, mixing chemicals from adjacent reagent areas and/or soiling hands with the urine control. See illustration 2 below.

3. Compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

#### Note:

- Results may be read up to 2 minutes after the specified times.
- Results may also be read using the Mission® and Mission® Expert Urine Analyzers. Refer to the Instruction Manual for details.

4. Clean the dropper tip, and immediately replace the cap tightly.



### EXPECTED VALUES

The expected values listed on the following page should only be used for the specific lots printed. Expected values were obtained from replicate analysis. The urine control and urinalysis reagent strip lots can create slight differences in expected results. Different laboratory methods, instruments and reagents can create variations between laboratories and variations over time. Use the results provided as reference only. It is recommended that each laboratory establish its own parameters of precision.

**Note:** The color reactions of Urobilinogen and Bilirubin reagent areas on the urinalysis reagent strips may produce colors that are atypical when visually compared to the color blocks on the color chart.

### LIMITATIONS

The Mission® Liquid Urine Control can only be used with Mission® and Mission® Expert Urinalysis Reagent Strips and Urine Analyzers. Ensure reproducible results by inverting the urine control bottle 3 times before each use. Interpretation of visual results depends on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the color chart does not correspond to a specific concentration, but it does correspond to a range of analyte concentrations.

### Index of Symbols

	Consult instructions for use		Tests per kit		Manufacturer
	For in vitro diagnostic use only		Use by		Authorized Representative
	Store between 2-8°C		Lot Number		Catalog #

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



**MDSS GmbH**  
Schiffgraben 41  
30175 Hannover, Germany

Number: 1150529004  
Effective date: 2013-02-16

# Mission® Urinalysis Reagent Strips and Urine Analyzers

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

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



**ACON®**

Global Diagnostics for Local Markets™



# Urinalysis Reagent Strips

## Simple and Accurate

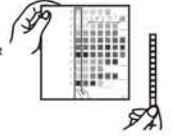
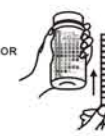
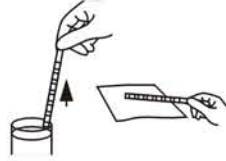
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

## Flexible

- Compatible for visual and analyzer reading
- More than 30 different combinations available

## Multiple Packaging Options and Long Shelf Life

- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging *New!*
  - Single-strip Pouch
    - Individually packaged strips with 1, 3, 6 and 20 strips and 1 color chart per kit for OTC or low volume testing
    - Unique packaging maintains 2 year shelf life for all strips in the kit compared to 3 months for remaining strips in an opened canister
  - Multi-strip Pouch
    - Canister Refill Kits with 25 strips/pouch uniquely packaged to save cost for low volume testing and extended shelf life by using the canister for refills



Step 1: Immerse strip into urine

Step 2: Remove excess urine

Step 3: Obtain results by analyzer or visual reading

Catalog No.	No. of Parameters	Type of Strip <sup>♦</sup>		Strips per Canister <sup>◇</sup>	Pouch Packaging <sup>▲</sup>	Reading Method			Analyzer-Read Strips: Standard (S) or Additional (A)	Parameters															
		For Visual Reading	For Analyzer Reading (U120/U500)			Visual	U120	U500		ASC	GLU	BIL	KET	SG	BLO	pH	PRO	URO	NIT	LEU	ALB	CRE			
U031-131	13	13C	NA	100*	✓	✓	NA	NA	A	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
U031-111	11		11A	100	✓	✓	✓	✓	S	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
U031-101	10		10U	100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*	*	*		
			10A			✓	✓	✓	A	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
			10C			✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-091	9		9U	100	✓	✓	✓	✓	S		*	*	*	*	*	*	*	*	*	*	*	*	*		
U031-081	8		8U	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*		
			8N			✓	✓	✓	S	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
			8S			✓	✓	✓	A	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-071	7		7N	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*		
U031-061	6	6N	6NE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*		
		6U	6UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-051	5	5B	5BE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*		
		5N	5NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*		
		5S	5SE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	
		5U	5UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-041	4	4S	4SE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*		
		4B	4BE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*		
		4K	4KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	
		4G	4GE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
		4N	4NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-031	3	3P	3PE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*		
		3K	3KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*		
		3G	3GE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	
		3N	3NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-021	2	2G	2GE	100	✓	✓	✓	✓	A		*	*	*	*	*	*	*	*	*	*	*	*	*		
		2K	2KE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	
		2N	2NE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
		2B	2BE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
		2U	2UE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
		2S	2SE			✓	✓	✓			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-011	1	1B	1BE	100	✓	✓	✓	✓	A					*											
		1P	1PE			✓	✓	✓						*											
		1G	1GE			✓	✓	✓			*														
		1K	1KE			✓	✓	✓				*													
		1R	1RE			✓	✓	✓									*								

♦Type of Strip:  
 Visual Strip Size  
 1-6 Parameters: 5 mm x 80 mm; 7-11 Parameters: 5 mm x 108 mm;  
 12-13 Parameters: 5 mm x 121 mm  
 U120/U500 Strip Size  
 1-11 Parameters: 5 mm x 108 mm;  
 "E" means extended strip length for 1-6 Parameters

◇ Also available in canisters of 25, 50 and 150 strips  
 \* Not available in canisters of 150 strips  
 ▲ Single-strip Pouch available in 1, 3, 6 and 20 strip kit  
 Canister Refill Kit, with 25 strips per pouch or canister, available in 3-pouch and 1- canister kit, or 4-pouch kit





# U120 Urine Analyzer



## Accurate

- Up to 120 tests/hour in Continuous Test Option
- Capable of reading 1 strip at a time in Single Test Option
- Test modes include Routine, STAT and QC
- Automatic calibration for accurate results and easy operation

## Reliable

- Can read up to 4 Strip combinations with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request
- Minimal training required

## Convenient Operation

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

## Easy Data Management

- Includes RS232C port for easy data transfer to an external computer or LIS
- Optional Barcode Reader to record patient ID

## Unique Lockout Functions *new!*

- Strip Lockout
  - Prevents using strips of another brand on the U120 Urine Analyzer
  - Requires barcode reader scan or manual entry of the canister code
- User Lockout
  - Eliminates unapproved users from testing
  - Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings
- QC Lockout
  - Prevents testing without passing QC
  - QC tests can be performed once every 8 hours, day, week or month
  - Analyzer will alert when to run QC test
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

## Specifications

Feature	Specifications
Analyzer Type	Manual
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	Single Test Option: 60 tests/hour Continuous Test Option: 120 tests/hour
Test Modes	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 results
Strip Incubation Time	1 Minute
Wavelength of Monochromatic LED	525 nm and 635 nm
Standard Strips	8, 9, 10, 11 Parameters (5 mm x 108 mm)
Additional Strips Available	1-11 Parameters (5 mm x 108 mm); see URS Parameters
Total Combinations Per Analyzer	4 Combinations
Analyzer Ports	Standard RS232C Port for Barcode Reader or Data Transfer USB Port for Data Transfer 25 Pin Parallel Port for External Printer
Capabilities	Internal Thermal Printer (included)      RS232C Barcode Reader (optional) Optional External Printer (not included)      USB or RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), Interleaved 25, UPC-A, UPC-E, EAN 8, EAN 13
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤ 85% RH
Storage Conditions	-5-50°C (23-122°F); ≤ 90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	27.2 cm x 26.9 cm x 14.6 cm (10.7" x 10.6" x 5.7")
Display Dimensions (L x W)	10.8 cm x 5.7 cm (4.2" x 2.2")
Weight	2.6 kg (5.7 lbs)

## Ordering Information

Product Name	Catalog No.	Components	Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U120 Urine Analyzer	U111-101 <sup>†</sup>	1 Urine Analyzer 2 Strip holder 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Quick Start Guide 1 Instruction Manual	42.0 cm x 41.5 cm x 31 cm; 5.0 kg 16.4" x 16.2" x 12.1"; 176.4 oz	1
U120 Urine Analyzer with Barcode Reader	U111-111 <sup>†</sup>	1 Urine Analyzer 1 Strip holder 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Quick Start Guide 1 Instruction Manual	44.5 cm x 44.5 cm x 40.0 cm; 5.5 kg 17.5" x 17.5" x 15.7"; 194 oz	1
Barcode Reader	U221-111 <sup>†</sup>	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg 9.3" x 4.3" x 3.1"; 17.0 oz 63.0 cm x 37.0 cm x 30.0 cm; 12.0 kg 24.8" x 14.6" x 11.8"; 423.3 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.36 kg 4.7" x 4.7" x 2.6"; 12.7 oz 63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz 12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg 4.7" x 4.7" x 2.6"; 14.1 oz 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	50
U120 Data Transfer Kit	U221-131 <sup>†</sup>	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg 6.3" x 5.1" x 1.4"; 5.2 oz 25.0 cm x 21.0 cm x 15.0 cm; 1.36 kg 9.8" x 8.3" x 5.9"; 48.0 oz	8

✓ CE Marked for sale in the European Community **CE**  
 † Cleared for US 510(k)

# U500 Urine Analyzer



## Accurate and Efficient

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

## Easy to Operate

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

## Convenient

- Automatic calibration and waste disposal reduce hands-on time
- Can read strips with 8, 9, 10, 11 parameters, additional strips with 1-11 parameters available upon request
- Strip selection of up to 4 combinations for analyzer reading
- Stores up to 2,000 records and automatically flags abnormal results
- Capable of printing results on sticker paper for quick and easy record management

## Data Management Capability

- Includes RS232C port for easy data transfer to an external computer or LIS
- Optional Barcode Reader to record patient ID

## Unique Lockout Functions Coming Soon!

- Strip Lockout
  - Prevents using strips of another brand on the U500 Urine Analyzer
  - Requires barcode reader scan or manual entry of the canister code
- User Lockout
  - Eliminates unapproved users from testing
  - Up to 10 lab operators can perform testing, but only the lab administrator can change analyzer settings
- QC Lockout
  - Prevents testing without passing QC
  - QC tests can be performed once every 8 hours, day, week or month
  - Analyzer will alert when to run QC test
  - If QC tests fail, analyzer will switch to STAT mode and list "E" at the end of each test number

## Specifications

Feature	Specifications
Analyzer Type	Semi-Automatic
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	500 tests/hour (Measuring cycle: 7 seconds/test)
Test Modes	Routine, STAT and QC
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 Records
Strip Incubation Time	1 Minute
Wavelength	525 and 635 nm
Standard Strips	8, 9, 10, 11 Parameters (5 mm x 108 mm)
Additional Strips Available	1-11 Parameters (5 mm x 108 mm); see URS Parameters
Total Combinations Per Analyzer	4 Combinations
Waste Disposal Capacity	Up to 150 Strips
Analyzer Ports	Standard RS232C Port for Barcode Reader or Data Transfer 25 Pin Parallel Port for External Printer
Capabilities	Internal Thermal Printer (included)      RS232C Barcode Reader (optional) Optional External Printer (not included)      RS232C Data Transfer Cable (optional)
Major Readable Barcodes	Code 128, Code 39, Codabar (NW-7), Interleaved 25, UPC-A, UPC-E, EAN 8, EAN 13
Calibration	Automatic
Available Languages on the Screen	English and additional language(s)
Operating Conditions	0-40°C (32-104°F); ≤85% RH
Storage Conditions	-5-50°C (23-122°F); ≤90% RH
Power Source	100-240 VAC, 50-60 Hz
Dimensions (L x W x H)	36.6 cm x 28.3 cm x 19.5cm (14.4" x 11.1" x 7.7")
Display Dimensions (L x W)	11.5 cm x 9.0 cm (4.5" x 3.5")
Weight	4.0 kg (8.8 lbs)

## Ordering Information

Product Name	Catalog No.	Components	Kit Box Dimensions (L x W x H) & Weight	Carton Dimensions (L x W x H) & Weight	Number of Kits/Carton
U500 Urine Analyzer	U211-101 <sup>✓</sup>	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual	51.0 cm x 42.0 cm x 38.5 cm; 7 kg 20.1" X 16.5" x 15.2"; 246.9 oz	1
U500 Urine Analyzer with Barcode Reader	U211-111 <sup>✓</sup>	1 Urine Analyzer 1 Strip Platform/Waste Tray 2 Printer Paper Rolls 1 Barcode Reader (RS232C)	2 Fuses (2.0A) 1 Power Cord 1 Serial Splitter Cable (RS232C) 1 Instruction Manual	55.0 cm x 55.0 cm x 55.0cm; 9.2 kg 21.7" x 21.7" x 21.7"; 324.5 oz	1
Barcode Reader	U221-111 <sup>✓†</sup>	1 Barcode Reader (RS232C)	1 Serial Splitter Cable (RS232C)	23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg 9.3" x 4.3" x 3.1"; 17.0 oz	22
Printer Paper Rolls	U121-101	4 Printer Paper Rolls	Thermal Paper (0.06 m x 20 m): 200 results/roll Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg 4.7" x 4.7" x 2.6"; 12.7oz 63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz 12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg 4.7" x 4.7" x 2.6"; 14.1oz 63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg 24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz	50
U500 Data Transfer Kit	U221-131 <sup>✓</sup>	1 Data Transfer Cable (RS232C)	1 Package Insert	16.0 cm x 13.0 cm x 3.5 cm; 0.147kg 6.3" x 5.1" x 1.4"; 5.2 oz	8

## We also offer other rapid diagnostic and medical products:

Blood Glucose Monitoring Systems, Immunoassay EIA/ELISA and more.

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† Cleared for US 510(k)





# Mission®

## Urine Controls

Simply validate visual and analyzer urinalysis with *Mission®* Liquid and Dry Strip Urine Controls!

- *Reliable*
- *Quick and Easy*
- *Available in Liquid and Dry Strip*



**ACON®**

Global Diagnostics for Local Markets™

# Mission® Urine Controls

## Reliable

- Use with *Mission®* and *Mission® Expert* Urinalysis Reagent Strips and Urine Analyzers for optimum quality control
- Validate urinalysis results and prevent procedure errors
- Control Level 1 provides negative results for LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB<sup>test</sup> and CRE<sup>test</sup>
- Control Level 2 provides positive results for LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB<sup>test</sup> and CRE<sup>test</sup> with negative results for ASC

## Quick and Convenient Testing

- Ensures accurate results for all parameters
- Obtain quick results in any setting
- Competitively priced

## Two Types of Urine Controls Available

### Liquid Urine Control

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

### Dry Strip Urine Control

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



## Specifications

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

## Ordering Information

Product Name	Catalog No.	Components	Kit Box Dimensions (LxWxH) & Weight	Carton Dimensions (LxWxH) & Weight	# Kits/Carton
Liquid Urine Control <sup>√†</sup>	U021-011: Combo	Level 1: 3 x 10 mL/bottle; Level 2: 3 x 10 mL/bottle	85 mm x 55 mm x 60 mm; 107 g	400 mm x 270 mm x 345 mm; 5.2 kg	198
		Level 1: 3 x 5 mL/bottle; Level 2: 3 x 5 mL/bottle	85 mm x 55 mm x 60 mm; 75 g	400 mm x 270 mm x 345 mm; 4.2 kg	198
		Level 1: 1 x 10 mL/bottle; Level 2: 1 x 10 mL/bottle	55 mm x 28 mm x 60 mm; 41 g	400 mm x 270 mm x 345 mm; 6.6 kg	228
		Level 1: 1 x 5 mL/bottle; Level 2: 1 x 5 mL/bottle	55 mm x 28 mm x 60 mm; 31 g	400 mm x 270 mm x 345 mm; 5.5 kg	228
	U021-021: Level 1; U021-031: Level 2	6 x 10 mL/bottle	85 mm x 55 mm x 60 mm; 107 g	400 mm x 270 mm x 345 mm; 5.2 kg	198
		6 x 5 mL/bottle	85 mm x 55 mm x 60 mm; 75 g	400 mm x 270 mm x 345 mm; 4.2 kg	198
		2 x 10 mL/bottle	55 mm x 28 mm x 60 mm; 41 g	400 mm x 270 mm x 345 mm; 6.6 kg	228
		2 x 5 mL/bottle	55 mm x 28 mm x 60 mm; 31 g	400 mm x 270 mm x 345 mm; 5.5 kg	228
Liquid Diptube Urine Control <sup>√†</sup>	U021-071: Combo	Level 1: 2 x 12 mL/diptube; Level 2: 2 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 101 g	385 mm x 255 mm x 320 mm; 4.7 kg	30
		Level 1: 1 x 12 mL/diptube; Level 2: 1 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 62 g	385 mm x 255 mm x 320 mm; 3.5 kg	30
	U021-081: Level 1; U021-091: Level 2	4 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 101 g	385 mm x 255 mm x 320 mm; 4.7 kg	30
Dry Strip Urine Control <sup>√†</sup>	U021-041: Combo	Level 1: 1 x 25 strips/canister; Level 2: 1 x 25 strips/canister	100 mm x 51 mm x 110 mm; 126 g	280 mm x 280 mm x 260 mm; 3.6 kg	24
		Level 1: 1 x 10 strips/canister; Level 2: 1 x 10 strips/canister	100 mm x 51 mm x 110 mm; 106 g	280 mm x 280 mm x 260 mm; 3.1 kg	24
	U021-051: Level 1; U021-061: Level 2	2 x 25 strips/canister	100 mm x 51 mm x 110 mm; 126 g	280 mm x 280 mm x 260 mm; 3.6 kg	24
		2 x 10 strips/canister	100 mm x 51 mm x 110 mm; 106 g	280 mm x 280 mm x 260 mm; 3.1 kg	24

√ CE Marked for sale in the European Community   
 † FDA 510(k) Cleared

**We also offer other rapid diagnostic and medical products for:**

Blood Glucose Monitoring Systems, Clinical Chemistry including Urinalysis, Immunoassay EIA/ELISA and more.

**Contact us for worldwide distribution and custom manufacturing (OEM) opportunities**







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

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## STATEMENT

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

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

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

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21



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



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

CE-DOC-OG039  
Version 1.0



# EC Declaration of Conformity

In accordance with Directive 98/79/EC

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

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

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

H. pylori Ag Rapid Test Strip (Feces)	GCHP-601a
H. pylori Ag Rapid Test Cassette (Feces)	GCHP-602a

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

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

We hereby explicitly appoint

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

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

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

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

Date Signed: November 28, 2017

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



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



CE-DOC-OG060  
Version 1.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

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

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

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

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

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

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

We hereby explicitly appoint

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

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

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

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

Date Signed: November 28, 2017

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



# Certificate

No. Q5 092305 0001 Rev. 01

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

**Certification Mark:**



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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_092305_0001_Rev.01)

**Report No.:** SH2198802

**Valid from:** 2022-04-11

**Valid until:** 2024-03-16

**Date,** 2022-04-11



Christoph Dicks

Head of Certification/Notified Body





Product Service

# Certificate

No. Q5 092305 0001 Rev. 01

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

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

See Scope of Certificate

# H. pylori Ag Rapid Test Cassette (Feces)



## INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in feces. It is for professional *in vitro* diagnostic use only.

## INTRODUCTION

H. Pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis.<sup>1,2</sup> The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer.<sup>3</sup> H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses<sup>4,5,6</sup> which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence.<sup>7</sup>

## PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori conjugates). 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. Otherwise, the test result is invalid and the specimen must be retested with another device.

## PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H. pylori antibodies particles and anti-H. pylori antibodies coated on the membrane.

## MATERIALS SUPPLIED

- 20 Sealed pouches each containing a test cassette and a desiccant
- 20 Specimen collection tubes with extraction buffer, 2.0 mL
- 1 Package insert

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Specimen collection containers.

## STORAGE AND STABILITY

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

## WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

## SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

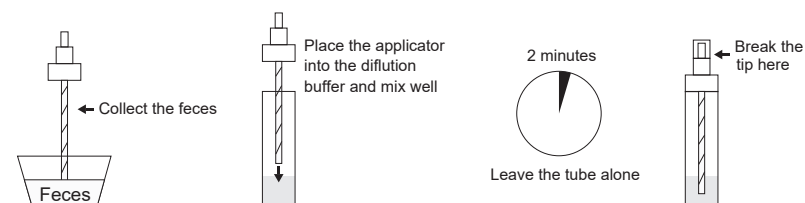
To process fecal specimens:

• For Solid Specimens:

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

• For Liquid Specimens:

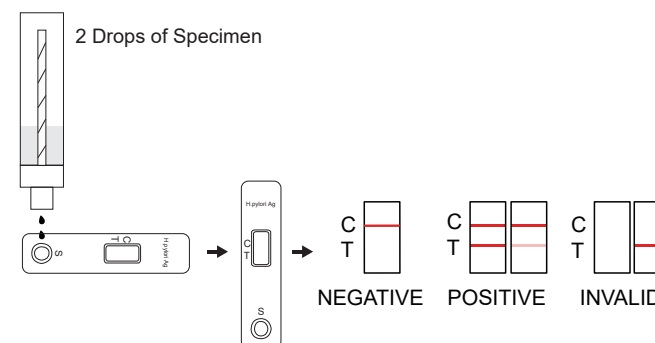
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.



## TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80 µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

## INTERPRETATION OF RESULTS



# H. pylori Ag Rapid Test Cassette (Feces)

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

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

Invalid: Control line fails to appear.

## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.

2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.

3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.

4. A negative result can occur if the quantity of the H. Pylori antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.

5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

## PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples. Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 98.8%

Relative specificity: 100%

Accuracy:98.9%

## REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.

2. Marshall,B.J.et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet. Dec.1437-42,1988.

3. Megraud,F.et.al. Seroepidemiology of Campylobacter pylori infection in virious populations J.Clin.Microbiology. 27:1870-3,1989.










4. Soll,A.H. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.322:909-916,1990.

5. Parsonnet,J.et.al. Helicobacter pylori infection and the risk of gastric carcinoma. New England J.Med. 325:1127-31,1991.

6. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991.


7. Pronovost,A.P.et.al. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J.Clin.Microbiol.32:46-50,1994.

## INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#



Zhejiang Orient Gene Biotech Co.,Ltd  
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Website: www.orientgene.com

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

 GCHP-602a

Revision Date: 2022-03-08  
B20435-03



Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



MEDICAL INSTRUMENTS  
PRODUCTION+TRADING GMBH

Dieselstraße 1  
D-84088 Neufahrn N.B.  
fon: +49-8773/707 80-0  
fax: +49-8773/707 80-29

## TO WHOM IT MAY CONCERN

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

### Distribution / Service Authorisation for the years 2019 - 2023

This letter confirms that company

**SANMEDICO SRL**  
Str. Petricani 88/1, oficiul 10  
Chisinau - Rep. Moldova MD-2059  
MOLDOVA  
Phone: 00373-22-623032  
Email: sanmedico.office@gmail.com

is the **authorized, exclusive and sole** representative of **TECO Medical Instruments, Production + Trading GmbH, Dieselstrasse 1, 84088 Neufahrn i.NB, Germany**, for the territory of **Moldova**, only for all TECO products listed below. **Sanmedico** may participate in public and privat tenders, providing sales to all TECO customers in the territory. We as manufacturer, certify that our **warranty and service** 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.

Validity: August 20<sup>th</sup>, 2019 to December 31<sup>st</sup>, 2023

Termination: Confirmation ends automatically on Dec. 31<sup>st</sup> of 2023 and must be then renewed.

#### TECO products:

- Coatron X (Eco, Pro, Top) new manual Coagulometers (1, 2 and 4 channel)
- Coatron A4, A6, A6 Plus Fully automated Coagulometers (4 and 6 channel)
- Complete line of Hemostasis Reagents, Consumables and Spareparts

This document is signed in Neufahrn, Germany, on August 20<sup>th</sup>, 2019.

TECO Medical Instruments, Production + Trading GmbH



MEDICAL INSTRUMENTS  
PRODUCTION+TRADING GMBH  
Dieselstraße 1  
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Christian Hoetzl  
General Manager





# KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Doc#200/08-2022

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

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

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

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

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

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

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

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

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



Christian Hötzl  
Verantwortliche Person / PRRC

Doc#200/08-2022

## KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Directive 98/79/EC Annex A

Übrige Produkte – Reagenzien für In-vitro-Diagnostika

Other products – Reagents for in vitro diagnostic – general IVD

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

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





# KONFORMITÄTSERKLÄRUNG

## DECLARATION OF CONFORMITY

Doc#100/07-2021

Wir / We

### TECO Medical Instruments Production and Trading GmbH

Name des Herstellers / Manufacturer's name  
**Dieselstrasse 1, 84088 Neufahrn, Germany**  
Anschrift / Address

erklären in alleiniger Verantwortung, dass die unten gelisteten IVD Zubehör Produkte:  
*declare under our own responsibility, that the IVD accessories products, listed below:*

Doppelküvette / <i>Double cuvette</i>	Ref. 19 000 02
Einzelküvette / <i>Single cuvette</i>	Ref. 20 000 02, 24 100 00
4-fach Küvette / <i>Cuvette 4 pos/ea</i>	Ref. 80 521 10
6-fach Küvette / <i>Cuvette 6 pos/ea</i>	Ref. 80 560 00
6-fach Küvette (micro) / <i>Cuvette 6 pos/ea (micro)</i>	Ref. 80 570 00

allen anwendbaren Anforderungen folgender Richtlinien entsprechen: *meet all applicable requirements of:*

1. Richtlinie 98/79/EG über In-vitro Diagnostika und ihrem Zubehör, klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"- im Sinne von Zubehör zu In vitro Diagnostika gemäß Artikel 1.

*1. Directive 98/79/EC on In-vitro diagnostic medical devices and their accessories, classified according to article 9 as: "all other products" – and in term of accessories for in vitro diagnostics according to article 1.*

2. Richtlinie 2011/65/EU (RoHS III)

*2. Directive 2011/65/EU (RoHS III)*

Das QM-System des Herstellers ist zertifiziert nach:

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

**EN ISO 13485:2016**

***EN ISO 13485:2016***

Konformitätsbewertungsverfahren gemäß:

*Conformity assessment procedure according to:*

Gemäß Anhang III der Richtlinie 98/79/EG

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

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

Neufahrn, 27.07.2021  
Neufahrn, July 27, 2021

Matthias Dieckmann  
General Manager





Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



MEDICAL INSTRUMENTS  
PRODUCTION+TRADING GMBH

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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. Hoetzi and Mrs. Wendy Guo**

---

Place of Training: **TECO – Germany**

Date: **November 18<sup>th</sup>, 2019**



Christian Hoetzi  
General Manager



# TECO

MEDICAL INSTRUMENTS  
PRODUCTION+TRADING GMBH

Dieselstraße 1  
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fon: +49-8773/707 80-0  
fax: +49-8773/707 80-29

Neufahrn, 26/04/2018

## TO WHOM IT MAY CONCERN

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



Christian Hoetzl  
General Manager  
TECO Germany

---

# Zertifikat

Hiermit wird bescheinigt, dass das Managementsystem von:

## **TECO Medical Instruments, Production + Trading GmbH**

Dieselstr. 1, 84088 Neufahrn, Deutschland

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

**ISO 13485:2016**

Gültigkeits-Nr.: ISO 13485 – 00038268

**Das Managementsystem ist anwendbar für:**

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



**Paul Graaf**

---

Area Operations Manager, Europe

Ausgestellt von: LRQA Limited



0001



TOP  
INNOVATION  
2017 - 2018

Clotting  
Chromogenic  
Immunturbidimetric

# Coatron

Semi-automated  
Coagulation Analyzer Series

With 1, 2 or 4 optical channels



# TECO

Innovation in Coagulation

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

The Coatron X instrument line is a consequent continuation in the development of the Coatron product line. Over 25 years in experience and innovation is the reference for our new Coatron X instrumentation line.

The unique detection principle in combination with the high-level analytical algorithm calculates exact, precise and reproducible results.

Easy in operation – self instructing user dialogue - reliable

## **Highest optical resolution, enlarged optic range, smallest sample and reagent volume**

0.1 mOD, 0 - 3800 mOD, just with 75 µL sample and reagent volume

## **Complete optical analysis**

No further parts required, like balls, stirrers etc.

## **Adaptation of the light level**

Automatic light level adjustment of the optic channels to each sample

## **Exclusion of disturbance**

Stray light reduction, exact temperature control, all parameter are preset



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

Coatron X - product family



With 1, 2 or 4 optical channels.

[www.teco-medical.com](http://www.teco-medical.com)

## Prepared for the daily routine and the upcoming requirements

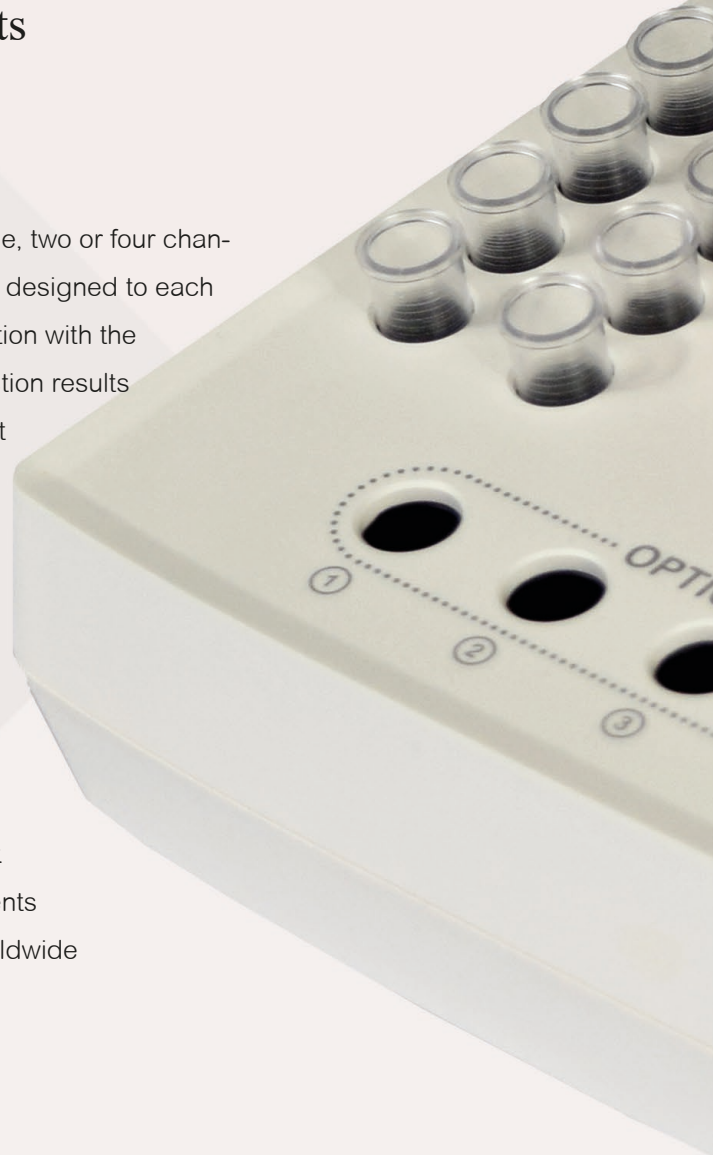
### One instrument – many possibilities

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



### Quality is our basic demand

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



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

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





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



## The details make the difference

### Coatron X

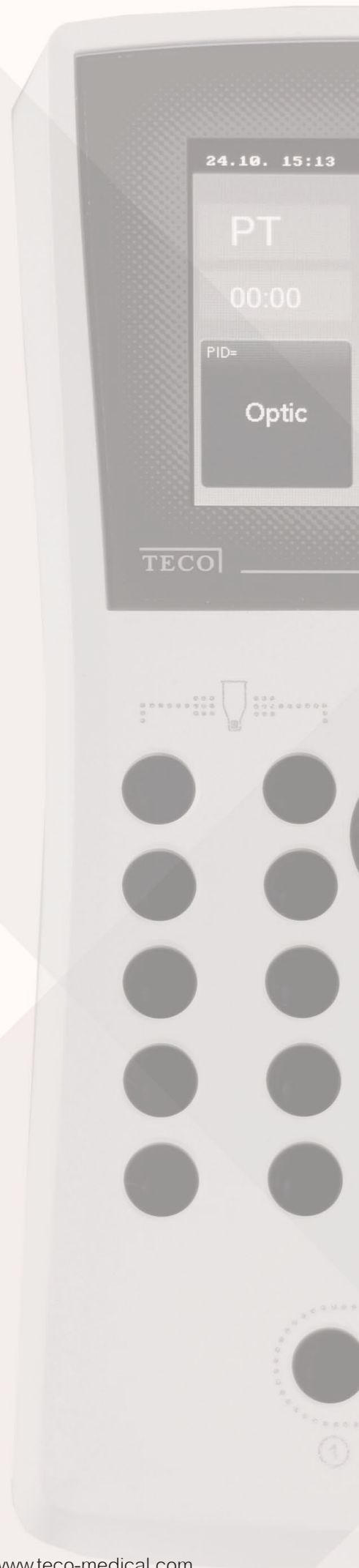
The remarkable details in every single component is achieved by selecting of premium suppliers.

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

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

### Software and connection possibilities

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



## Operation details

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





### Intuitive operation and control

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

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



### For small and mediate laboratory requirements

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

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

### Interfaces

#### RS232 (2x)

- For external serial printer and external barcodereader

#### LIS/USB

#### Bluetooth



Integrated barcode scan for reagents.





### **TECO Cloud Services**

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

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



For trading partners worldwide, please visit our web-page

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**TECO**  
Innovation in Coagulation



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<sup>1,2</sup>. 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<sup>4</sup>**

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

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

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

Prothrombin Time		A4		A6				A4		A6	
PAT	Patient	50µl	CP1	25µl	CP1	Incubation	0s	SENS	2		
BUF	IBS Buffer	0µl	P39	0µl	P79	Maxtime	120s	POINTS	4		
CLR	-	0µl	-	0µl	-	Unit	251	MIX	No		
DP	-	0µl	P00	0µl	P00	Method	Coag	Clean	0	0	
R0	-	0µl	P00	0µl	P00	Math	log XY	Multi	1	3	
R1	-	0µl	P00	0µl	P00	CT-Mech	No	S-Corr	0%		
R2	PT Reagent	100µl	P25	50µl	P46	Deadtime	7s	T-Corr	30% - 4s		

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

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

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

**Symbol keys**

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

**Expected Results**

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

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

**Standardisation and Calibration**

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

**INR results:**

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

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

**Activity % (Quick) result:**

were calculated from a calibration curve, which is prepared from reference plasma (e.g. TECAL N) and dilutions in saline solution like 0.9% NaCl<sub>2</sub> 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%.<sup>5</sup>

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

**Quality Control**

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

**Limitations**

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

**A. Specimen Collection. AVOID:**

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

**B. Laboratory Techniques**

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

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

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

**Warranty**

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

**References**

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







IVD

REF

A0300-025, A0300-050, A0320-050, A0320-100

**Intended Use**

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

**Contents & Determinations**

Product	TEClot APTT-S Kit-25	TEClot APTT-S Kit-50	TEClot APTT-S A0320-050	TEClot APTT-S A0320-100
Cat.No.	A0300-025	A0300-050	A0320-050	A0320-100
APTT-S Reagent*	5x5 mL	5x10 mL	10x5 mL	10x10 mL
CaCl <sub>2</sub> 0.025M**	5x5 mL	5x10 mL	-	-

**Determinations**

Coatrom M***	1000 Det.	2000 Det.	2000 Det.	4000 Det.
Coatrom A4	500 Det.	1000 Det.	1000 Det.	2000 Det.
Coatrom A6	1000 Det.	2000 Det.	2000 Det.	4000 Det.

\*APTT-S Reagent contains colloidal silicate with phospholipids, buffer and preservatives.

\*\*CaCl<sub>2</sub> contains sodium azide.

\*\*\*Micro method (75µl in total)

**Preparation**

Components of kit are ready to use. Allow CaCl<sub>2</sub> to prewarm 15 min at 37 °C and mix APTT reagent gently prior usage

**Storage & Stability**

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

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

**Precautions**

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

**Specimen collection and storage<sup>5</sup>**

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

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

**Procedure****A. Automated Method: Coatrom A**

APTT-S		A4		A6		A4		A6	
PAT	Patient	50µl	CP1	25µl	CP1				
BUF	-	0µl	P00	0µl	P00	Incubation	180s	SENS	1
CLR	-	0µl	-	0µl	-	Maxtime	180s	POINTS	0
DP	-	0µl	P00	0µl	P00	Unit	17	MIX	No
R0	-	0µl	P00	0µl	P00	Method	Coag	Clean	0   0
R1	APTT-S	50µl	P31	25µl	P60	Math	-	Multi	1   3
R2	CaCl 25mM	50µl	P26	25µl	P47	CT-Mech	No	S-Corr	0%
						Deadtime	17s	T-Corr	15% - 6s

**B. Manual Method: Coatrom M**

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

**Expected Results**

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

**Quality Control**

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). 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:**

- 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****Typical performance on instrument Coatrom M4**

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

**Factor & Heparin sensitivity:**

Factor (%)	APTT Clotting time (s)		
	FVIII	FIX	FXI
< 1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	358

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

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

**Warranty**

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

**References**

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

Symbols key:

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



# Calcium Chloride 0,025M

# TECO

**IVD****REF**

A0350-050, A0350-100

## Intended Use

This product is used in combination with reagent TEClot APTT-S (Cat.No. A0320) to determine the APTT or also for other 25mM CaCl<sub>2</sub> requiring coagulation tests.

## Contents & Determinations

Product	Calcium Chloride	Calcium Chloride
Cat.No.	A0350-050	A0350-100
CaCl <sub>2</sub> 0.025M	10x5 mL	10x10 mL

## Determinations

Coatron M	2000 Det.	4000 Det.
Coatron A	1000 Det.	2000 Det.

## Preparation

Ready to use.

## Storage and Stability

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

Opened reagent is stable for 30 days at 2-8°C in the original vial.

## Precautions

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

Calcium Chloride Solution contains sodium azide. Sodium azide under acid conditions yields Hydrazoic acid, an extremely toxic compound. Azide compounds should be diluted with running water before being discarded. Upon disposal, azide compounds should be flushed with large volumes of water. These precautions are recommended to avoid deposits in metal pipes in which explosive conditions may develop.

## Warranty

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

Symbols key:

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

# Calcium Chloride 0,025M

# TECO

**IVD****REF****A0350-050, A0350-100**

## Verwendungszweck

Wird zusammen mit dem Reagenz TEClot APTT-S (Kat. Nr. A0320) zur Bestimmung von der APTT verwendet oder auch für andere Gerinnungstests, für die 25mM CaCl<sub>2</sub> benötigt wird.

## Inhalt und Bestimmungen

Produkt	Kalzium Chlorid	Kalzium Chlorid
Kat. Nr.	A0350-050	A0350-100
CaCl <sub>2</sub> 0.025M	10x5 mL	10x10 mL

## Bestimmungen

Coatron M	2000 Det.	4000 Det.
Coatron A	1000 Det.	2000 Det.

## Vorbereitung

Das Reagenz ist gebrauchsfertig

## Lagerung und Stabilität

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

Geöffnete Reagenzien sind bei Lagerung zwischen 2-8°C im Originalfläschchen 30 Tage haltbar.

## Vorsichtsmaßnahmen

Haut- und Augenkontakt vermeiden. Schutzkleidung tragen. Abfälle unter Beachtung der vorgeschriebenen internationalen, nationalen und lokalen Bestimmungen entsorgen.

Die Calcium Chlorid Lösung enthält Natriumazid. Unter sauren Bedingungen setzt Natriumazid Hydrogenazid frei, ein höchst giftiger Wirkstoff. Azidverbindungen sollten unter laufendem Wasser gelöst werden bevor sie entsorgt werden. Diese Vorsichtsmaßnahmen werden empfohlen, um Ablagerungen in Metallrohren zu verhindern, die explosive Bedingungen entwickeln könnten.

## Garantie

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

Erklärung der Symbole:

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





IVD

REF

A0401-020

**Intended Use**

TEClot TT reagent can be used manually or on semi-automated and automated instruments. The test is commonly applied to detect various sources of interference with normal blood coagulation. Prolongation of the thrombin clotting time can be taken as a qualitative indication of abnormal fibrinogen levels (high or low), or the presence of interfering substances such as FDP's or heparin. Quantitative evaluation of the possible causes of prolonged thrombin clotting time should be performed as follow-up studies, such as APTT or chromogenic assay for heparin, Clauss fibrinogen, FDP determinations, heparin neutralization by protamine sulphate or polybrene<sup>1</sup>, normal plasma mixing studies<sup>2</sup> or reptilase assay<sup>3</sup> to distinguish between hypofibrinogenemia and FDP effects.

**Contents & Determinations**

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

**Determinations**

Coatron M	Coatron A4	Coatron A6
800	400	800

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

**Preparation**

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

**Storage & Stability**

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

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

The vials can be only frozen once.

**Precautions**

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

**Specimen collection and storage<sup>4</sup>**

- 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/ $\mu$ L)
- Separate plasma after centrifugation and store in plastic or siliconised glass tube.
- Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

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

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

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

(Refer to instrument operation manual for detailed instructions)

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

- Pipette **50  $\mu$ l of sample** into a test cuvette. Incubate at 37°C for 1-2 minutes.
- Add **25  $\mu$ l of TEClot TT** reagent and simultaneously start test.
- Record the clotting time in seconds.

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

**Expected Results**

Typical normal results are 12 – 24 s<sup>6</sup>. 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  $\mu$ l stored in closed polypropylen tubes at -20°C is stable for 30 days

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

- Use only plastic tubes or siliconised glass.
- Delayed mixing of blood with anticoagulant.
- Contamination with tissue thromboplastin.
- Improper ratio of anticoagulant with blood.
- Hemolyzed, icteric or lipemic samples may interfere optical systems
- Heparin below 1U/mL will not interfere results.

**B. Laboratory Techniques**

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

As well as the cause of elongated Thrombin Clotting Times indicated above, a recent report has suggested that many systemic amyloidosis patients with bleeding complications may have a circulating inhibitor which prolongs the Thrombin Clotting Time<sup>5</sup>. Also therapeutic levels of heparin may entirely abolish clotting in the Thrombin Clotting Time test, although neutralization with protamine sulphate or polybrene should correct the Thrombin Clotting Time<sup>1</sup>.

**Performance Characteristics**

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

(Typical performance on instrument Coatron M4)

**Warranty**

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

**References**

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

Symbols key:

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





IVD

REF

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

### Intended Use

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

### Contents & Preparation

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

### Determinations

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

\*Micro method (75µl in total)

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



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

### Storage & Stability

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

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

\* Reagent must be protected from UV-light and evaporation

### Precautions

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

### Specimen collection and storage<sup>3</sup>

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

### Procedure

#### A. Automated Method. Coatron A

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

### B. Manual Method: Coatron M

- 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

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

- 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<sup>4,5</sup>. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

### Quality Control

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

### Limitations

- Specimen Collection. AVOID:
  - Use only plastic tubes or siliconised glass.
  - Delayed mixing of blood with anticoagulant.
  - Contamination with tissue thromboplastin.
  - Improper ratio of anticoagulant with blood.
  - Hemolyzed, icteric or lipemic samples may interfere optical systems
- Laboratory Techniques
  - Perform tests at 37°C.
  - Use only high purity water.
  - Optimum pH is 7.0-7.5.

### Performance Characteristics

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

(Typical performance on instrument Coatron M4)

### Warranty

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

### References

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

Symbols key:

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



IVD

REF

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

### Verwendungszweck

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

### Inhalte und Vorbereitungen

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

### Bestimmungen

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

\*Mikromethode (75µL insgesamt)

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

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

### Lagerung und Stabilität

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

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

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

### Vorsichtsmaßnahme

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

### Probenentnahme und Lagerung<sup>3</sup>

- Venöses Blut mittels Venenpunktur unter sauberen Bedingungen entnehmen.
- Sofort 9 Teile Blut mit einem Teil 3,2% Natriumzitrat (0,105M) gut mischen.
- Probe bei 1500g 10 Minuten lang zentrifugieren (Thrombozyten <10000/µl)
- Plasma nach der 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	
PAT	Patient	10µl	CP1	10µl	CP1	Incubation	0s	SENS	0		
BUF	IBS Buffer	90µl	P39	90µl	P79	Maxtime	120s	POINTS	4		
CLR	-	0µl	-	0µl	-	Unit	769	MIX	No		
DP	-	0µl	P00	0µl	P00	Method	Coag	Clean	1	3	
R0	-	0µl	P00	0µl	P00	Math	log XY	Multi	1	1	
R1	-	0µl	P00	0µl	P00	CT-Mech	Yes	S-Corr	0%		
R2	Fibrinogen	50µl	P29	50µl	P49	Deadtime	3s	T-Corr	0%		

Erklärung der Symbole:

Verfallsdatum	IVD	In-Vitro Diagnostik	Biologische Gefahr	REF	Katalog-Nummer	i	Begleitpapiere beachten	
Bei 2-8°C lagern	CE	EU Konformität	Hersteller	LOT	Lot.-Nummer	EC	REP	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<sup>4,5</sup>. 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

<b>Präzision:</b>	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.





IVD

REF

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

**Revisions-Übersicht:**

Rev.	am	Änderung durch	Gültig für	Freigabe am	Freigabe durch
1	5.4.11	WG	Technoclone FIB		
	Beschreibung:	New box insert for Technoclone FIB.			
2	21.12.11	CB	Technoclone FIB	21.12.11	CH
	Beschreibung:	Neue Stabilitätsangaben. Die Vorgaben wurden dem Technoclone Stability Test Report „TC6E0C.01“ vom 5.5.2010 entnommen.			
3	11.11.13	CB	Technoclone FIB		
	Beschreibung:	<ul style="list-style-type: none"> <li>- Protokoll für A4+A6</li> <li>- Stabilitätsdaten neu</li> </ul>			
4	16.10.17	AR	Technoclone FIB	16.10.17	CH
	Beschreibung:	Technoclone Puffer (A0591-090) wird ersetzt durch IBS (A0590-125) (wegen deutlicher Messunterschiede bei Coatron A und X Serie) Wertermittlung für das CoA erfolgt ebenso mit IBS (A0590-125)			
5	23.01.18	VG	Technoclone FIB	23.01.18	VG
	Beschreibung:	Neue Stabilitätsangaben von Technoclone vom Thrombin Reagent.			



### Intended Use

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

### Contents & Determinations

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

### Preparation

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

### Storage and Stability

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











### Precautions

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

### Warranty

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

Symbols key:

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



A0590-125

### Verwendungszweck

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

### Inhalte und Bestimmungen

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

### Vorbereitung

IBS: pH 7.3 - 7.4, flüssig  
Gebrauchsfertig

### Lagerung und Stabilität

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

### Vorsichtsmaßnahmen

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

### Garantie

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

Erklärung der Symbole:

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





IVD

REF

P6001-010

**Intended Use**

Use as a normal control for following coagulation tests:

**PT, APTT, Thrombintime and Fibrinogen.**

**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 und Fibrinogen.**

**Inhalt**

10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

**Vorbereitung**

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

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

**Lagerung und Stabilität**

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

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

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

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

**Vorsichtsmaßnahmen**

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

**Erwartete Ergebnisse**

Lesen Sie das Analysenzertifikat

**Garantie**

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

Erklärung der Symbole:

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



IVD

REF

P6001-010

## Revisions-Übersicht:

Rev.	am	Änderung durch	Gültig für	Freigabe am	Freigabe durch
1	5.4.11	WG	Technoclone Coagulation Control N		
	Beschreibung:	New box insert for Technoclone Coagulation Control N.			





IVD

REF

P6101-010

**Intended Use**

Use as an abnormal control for following coagulation tests:

**PT, APTT, Thrombin time and Fibrinogen.**

**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



## Verwendungszweck

Als abnormale Kontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit und Fibrinogen.**

## 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

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Erklärung der Symbole:

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