# 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: March 18, 2024

Signature: 

Qiyi Xie, Md, MPH
V.P. of Regulatory & Clinical Affairs
ACON Laboratories, Inc.

Digitally signed by Dolgopol Iulian
Date: 2024.04.09 11:18:44 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

Product Service

# Certificate

## No. Q5 104507 0001 Rev. 03

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

**Certification Mark:**

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

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

**Report No.:** SH22743A01

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

**Date,** 2022-09-15

Christoph Dicks
Head of Certification/Notified Body


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

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

TÜV SÜD Product Service

# Certificate

## No. Q5 104507 0001 Rev. 03

**Applied Standard(s):**

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

**Facility(ies):**

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

Address holder for registration only

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

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

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

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

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

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

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

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

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

Product Service

# EC Certificate

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

## No. V1 104507 0003 Rev. 06

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

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

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

**Report no.:** SH22743EXT01

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

**Date,** 2022-05-04

Christoph Dicks
Head of Certification/Notified Body


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

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

Product Service

# EC Certificate

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

## No. V1 104507 0003 Rev. 06

**Model(s):**

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


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Product Service

# EC Certificate

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

## No. V1 104507 0003 Rev. 06

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

**Facility(ies):**

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

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

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

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

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

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# Declaration of Conformity

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

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

*Mission*® Urinalysis Reagent Strips (U031-XX1)

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

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

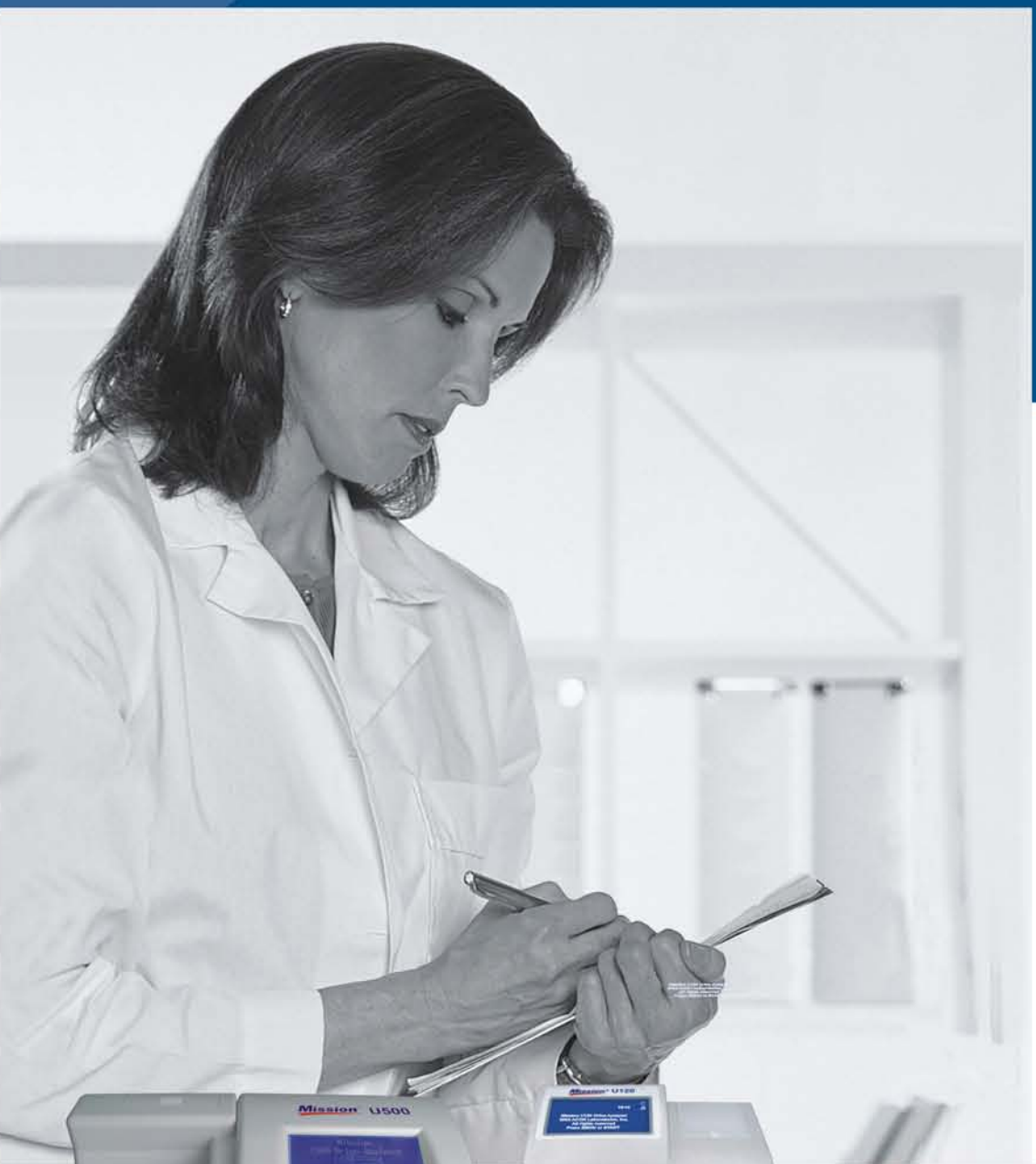
**The self-declaration is according to Annex III (excluding Section 6) of the Directive.**

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

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

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

# *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

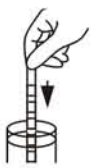
- Analytical sensitivity better than or comparable to market leaders
- High quality color chart ensures accurate visual reading

## Flexible

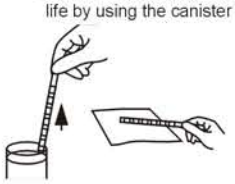
- Compatible for visual and analyzer reading
- More than 30 different combinations available

## Multiple Packaging Options and Long Shelf Life

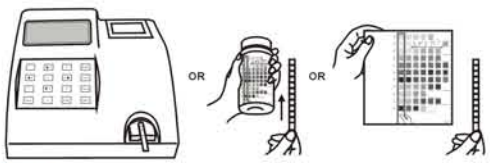
- Canister Packaging
  - Available in 25, 50, 100 and 150 strips per kit
  - 2 year shelf life for unopened canisters which offers cost savings and convenience for high volume testing
  - 3 month shelf life for strips in opened canisters
- Pouch Packaging ***New!***
  - Single-strip Pouch
    - Individually 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♦ | | Strips per Canister◇ | Pouch Packaging▲ | 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 | | 100■ | | ✓ | ✓ | ✓ | 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 | | | ✓ | ✓ | ✓ | | | | | | | * | | * | | * | * | | |
| | | 4P | 4PE | | | ✓ | ✓ | ✓ | | | * | | | | | | * | | * | * | | |
| 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 | | | ✓ | ✓ | ✓ | | | | | | * | | * | | | | | | | |
| | | 2C | 2CE | 100■ | | ✓ | ✓ | ✓ | | | | | | | | | | | | | | * | * |
| 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

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

# 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<br>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<br>USB Port for Data Transfer<br>25 Pin Parallel Port for External Printer |
| Capabilities | Internal Thermal Printer (included) RS232C Barcode Reader (optional)<br>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,<br>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√† | 1 Urine Analyzer<br>1 Strip holder<br>2 Printer Paper Rolls | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Quick Start Guide<br>1 Instruction Manual | 42.0 cm x 41.5 cm x 31 cm; 5.0 kg<br>16.4" x 16.2" x 12.1"; 176.4 oz | | 1 |
| U120 Urine Analyzer with Barcode Reader | U111-111√† | 1 Urine Analyzer<br>1 Strip holder<br>2 Printer Paper Rolls<br>1 Barcode Reader (RS232C) | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Serial Splitter Cable (RS232C)<br>1 Quick Start Guide<br>1 Instruction Manual | 44.5cm x 44.5cm x 40.0cm; 5.5 kg<br>17.5" x 17.5" x 15.7"; 194 oz | | 1 |
| Barcode Reader | U221-111√† | 1 Barcode Reader (RS232C) | 1 Serial Splitter Cable (RS232C) | 23.6 cm x 10.8 cm x 7.8 cm; 0.482 kg<br>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<br>24.8" x 14.6" x 11.8"; 423.3 oz | 22 |
| Printer Paper Rolls | U121-101 | 4 Printer Paper Rolls | Thermal Paper (0.06 m x 20 m): 200 results/roll | 12.0 cm x 12.0 cm x 6.5 cm; 0.36kg<br>4.7" x 4.7" x 2.6"; 12.7oz | 63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg<br>24.8" x 14.6" x 11.8"; 684.3 oz | 50 |
| | | | Sticker Paper (0.06 m x 9 m): 100 results/roll | 12.0 cm x 12.0 cm x 6.5 cm; 0.4 kg<br>4.7" x 4.7" x 2.6"; 14.1 oz | 63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg<br>24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz | |
| U120 Data Transfer Kit | U221-131√† | 1 Data Transfer Cable (RS232C) | 1 Package Insert | 16.0 cm x 13.0 cm x 3.5 cm; 0.147 kg<br>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<br>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<br>25 Pin Parallel Port for External Printer |
| Capabilities | Internal Thermal Printer (included) RS232C Barcode Reader (optional)<br>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√ | 1 Urine Analyzer<br>1 Strip Platform/Waste Tray<br>2 Printer Paper Rolls | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Instruction Manual | 51.0 cm x 42.0 cm x 38.5 cm; 7 kg<br>20.1" X 16.5" x 15.2"; 246.9 oz | | 1 |
| U500 Urine Analyzer with Barcode Reader | U211-111√ | 1 Urine Analyzer<br>1 Strip Platform/Waste Tray<br>2 Printer Paper Rolls<br>1 Barcode Reader (RS232C) | 2 Fuses (2.0A)<br>1 Power Cord<br>1 Serial Splitter Cable (RS232C)<br>1 Instruction Manual | 55.0 cm x 55.0 cm x 55.0cm; 9.2 kg<br>21.7" x 21.7" x 21.7"; 324.5 oz | | 1 |
| Barcode Reader | U221-111√† | 1 Barcode Reader (RS232C) | 1 Serial Splitter Cable (RS232C) | 23.6 cm x10.8 cm x 7.8 cm; 0. 482 kg<br>9.3" x 4.3" x 3.1"; 17.0 oz | 63.0 cm x 37.0 cm x 30.0 cm; 12 kg<br>24.8" x 14.6" x 11.8"; 423.3 oz | 22 |
| Printer Paper Rolls | U121-101 | 4 Printer Paper Rolls | Thermal Paper (0.06 m x 20 m): 200 results/roll | 12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg<br>4.7" x 4.7" x 2.6"; 12.7oz | 63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg<br>24.8" x 14.6" x 11.8"; 684.3 oz | 50 |
| | | | Sticker Paper (0.06 m x 9 m): 100 results/roll | 12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg<br>4.7" x 4.7" x 2.6"; 14.1oz | 63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg<br>24.8" x 14.6" x 11.8"; 684.3 oz; 754.9 oz | |
| U500 Data Transfer Kit | U221-131√ | 1 Data Transfer Cable (RS232C) | 1 Package Insert | 16.0 cm x 13.0 cm x 3.5 cm; 0.147kg<br>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<br>9.8" x 8.3" x 5.9"; 48.0 oz | 8 |

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1150449703

# Mission® Urinalysis Reagent Strips (Urine)

## Package Insert

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

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

## INTENDED USE

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

## SUMMARY

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

## PRINCIPLE AND EXPECTED VALUES

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

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

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

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

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

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

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

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

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

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

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

## REAGENTS AND PERFORMANCE CHARACTERISTICS

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

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

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

## PRECAUTIONS

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

## STORAGE AND STABILITY

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

## SPECIMEN COLLECTION AND PREPARATION

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

## MATERIALS

**Materials Provided**

- Strips
- Package insert

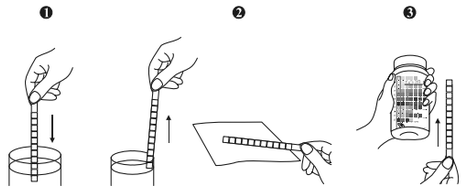
**Materials Required But Not Provided**

- Specimen collection container
- Timer

## DIRECTIONS FOR USE

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

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




## INTERPRETATION OF RESULTS

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

## QUALITY CONTROL

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

## LIMITATIONS

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

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**Index of Symbols**

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


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

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

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- Coatron M1 — Semi-automated 1-channel Coagulometer (out of production)
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- Coatron X Pro — Semi-automated 2-channel Coagulometer
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This document is signed in Neufahrn, Germany, on January 18th, 2023

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl

Medical Instruments TECO Production+Trading GmbH

| | | |
|---|---|---|
| Current issue date: | 10 November 2022 | Original approval(s): |
| Expiry date: | 9 November 2025 | ISO 13485 - 10 November 2022 |
| Certificate identity number: | 10479697 | |

# Certificate of Approval

This is to certify that the Management System of:

## TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

**ISO 13485:2016**

Approval number(s): ISO 13485 – 00038268

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

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

**Paul Graaf**

Area Operations Manager, Europe

Issued by: LRQA Limited

UKAS MANAGEMENT SYSTEMS 0001

# 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:
Place and date of issue: Neufahrn, 2022-08-31

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC



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Doc#200/08-2022

# KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

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

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

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



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Neufahrn, 26/04/2018

**TO WHOM IT MAY CONCERN**

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

Medical Instruments
TECO
Production+Trading GmbH

Christian Hoetzl
General Manager
TECO Germany

ISO 9001:2008 DEKRA Certification DEKRA certified

Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008

Quality Management EN ISO 13485 www.dekra-iasl.com DEKRA certified

TECO

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# CERTIFICATE

for: **Mr. Vitalie Goreacii**

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

have participated with success at the intensive training session:

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

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

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

Place of Training: TECO – Germany

Date: November 18th, 2019

Christian Hoetzl
General Manager

TOP
INNOVATION
2017 - 2018

Clotting
Chromogenic
Immunturbidimetric

# Coatron X

## Semi-automated
## Coagulation Analyzer Series

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


TECO
Innovation in Coagulation

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

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

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

TECO

Innovation in Coagulation

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

**Coatron X - product family**


With 1, 2 or 4 optical channels.

www.teco-medical.com

Coatron X

# Prepared for the daily routine and the upcoming requirements

**One instrument – many possibilities**

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

MADE IN GERMANY

**Quality is our basic demand**

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

TECO CLOUD

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

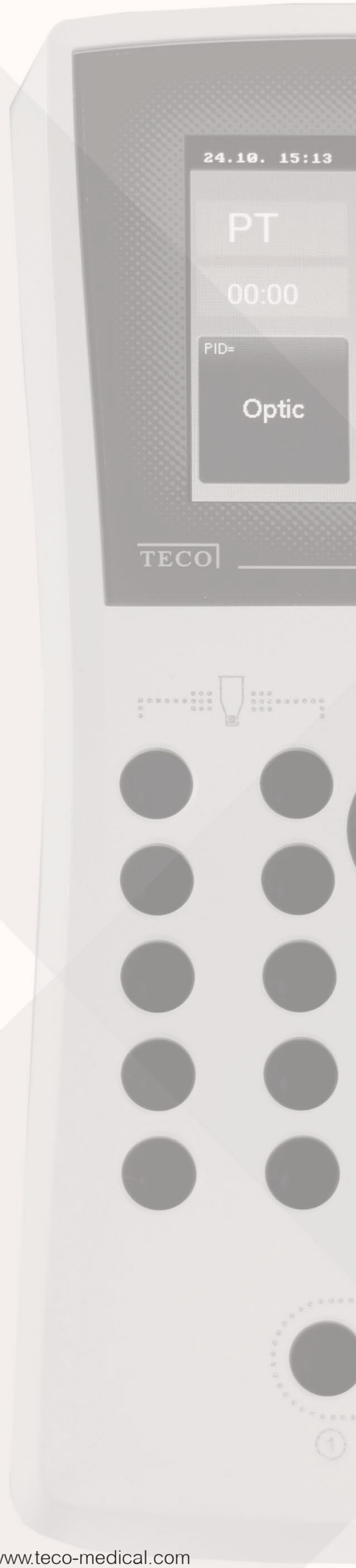
All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.


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

CE IVD

Coatron X

# The details make the difference




**Coatron X**

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

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

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

**Software and connection possibilities**

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

# Operation details

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


**Intuitive operation and control**

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

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


**For small and mediate laboratory requirements**

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

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

**Interfaces**

**RS232 (2x)**

- For external serial printer and external barcodereader

**LIS/USB**

**Bluetooth**


Integrated barcode scan for reagents.

TECO CLOUD

**TECO Cloud Services**

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

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

For trading partners worldwide, please visit our web-page

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TECO
Innovation in Coagulation

CoatronX-E-v0E

# TEClot PT-S

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

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

## Contents & Determinations

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

Determinations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## References

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


Symbol keys

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


TECO GmbH, Dieselstr. 1, 84088 Neufahrn NB Germany

# TEClot FIB

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

## Intended Use

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

## Contents & Preparation

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

Determinations

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

*Micro method (75µL in total)

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

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

## Storage & Stability

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

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

* Reagent must be protected from UV-light and evaporation

## Precautions

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

## Specimen collection and storage[3]

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

## Procedure

**A. Automated Method. Coatron A**

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

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

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

**B. Manual Method: Coatron M**

1. Preparation of Standard, Control and Patient Dilutions

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

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

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

## Calibration

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

## Expected Results

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

## Quality Control

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

## Limitations

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

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

## Performance Characteristics

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

(Typical performance on instrument Coatron M4)

## Warranty

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

## References


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


Symbols key:

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

# TEClot FIB

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

## Verwendungszweck

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

## Inhalte und Vorbereitungen

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

Bestimmungen

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

*Mikromethode (75µL insgesamt)

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

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

## Lagerung und Stabilität

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

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

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

## Vorsichtsmaßnahme

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

## Probenentnahme und Lagerung [3]

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

## Verfahren

**A. Automatenmethode: Coatron A**

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

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

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

**B. Manuelle Methode: Coatron M**

1. Vorbereitung von Standard-, Kontroll- und Patientenlösungen

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

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

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

## Kalibrierung

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

## Erwartete Ergebnisse

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

## Qualitätskontrolle

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

## Beschränkungen

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

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

## Leistungsdaten

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

(Typische Leistung beim Gerät Coatron M4)

## Garantie

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

## Referenzen


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


Erklärung der Symbole:

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

## Revisions-Übersicht:

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

# IBS Buffer

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

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

### Contents & Determinations

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

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

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

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

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

Symbols key:

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

# IBS Buffer

IVD REF *A0590-125*

## Verwendungszweck

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

## Inhalte und Bestimmungen

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

## Vorbereitung

IBS: pH 7.3 - 7.4, flüssig
Gebrauchsfertig

## Lagerung und Stabilität

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

## Vorsichtsmaßnahmen

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

## Garantie

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

Erklärung der Symbole:

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

# TEControl N

CE IVD REF **P6001-010**

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

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

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

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

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

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

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

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

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

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

## Expected Results
Refer to "Certificate of Analysis".

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

Symbols key:

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


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

# TEControl N

CE IVD REF P6001-010

## Verwendungszweck
Als normale Kontrolle für folgende Gerinnungstests verwenden:

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

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

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

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

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

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

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

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

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

## Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

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

Erklärung der Symbole:

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

# TEControl A

CE IVD REF P6101-010

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

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

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

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

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

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

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

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

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

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

## Expected Results
Refer to "Certificate of Analysis".

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

Symbols key:

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

# TEControl A

CE IVD REF P6101-010

## Verwendungszweck
Als abnormale Kontrolle für folgende Gerinnungstests verwenden:

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

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

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

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

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

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

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

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

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

## Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

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

Erklärung der Symbole:

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

# TECal N

IVD | REF P8001-005

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

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

## Contents
5 x 1mL freeze dried citrate-anticoagulated human plasma

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

PT whole blood (TEClot PT-B CAT=A0260 xxx): Reconstitute individual vials with **1,7 ml** distilled water.

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

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

| -20 °C | 2-8 °C | 20-25 °C | 37°C |
|---|---|---|---|
| 30 days | 24h | 8h | 2 hours |

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

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

## Performance Characteristics:
Refer to "Certificate of Analysis".

## Limitations:
The control plasma is subject to the limitations of the assay system (reagent + instrument). Results out of expected range may indicate deterioration, false test calibration or problems with one or more components of the test system

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

Symbols key:

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

# TECal N

CE | IVD | REF P8001-005

## Verwendungszweck
Als Kalibrator oder Normalkontrolle für folgende Gerinnungstests verwenden:

**PT, APTT, Thrombinzeit, Fibrinogen,**
**Faktoren: II, V, VII, VIII, IX, X, XI, XII,**
**Antithrombin, Protein-C, freies Protein-S,**
**D-Dimer**

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

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

Vollblut PT (TEClot PT-B CAT=A0260 xxx): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

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

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

| -20 °C | 2-8 °C | 20-25 °C | 37°C |
|---|---|---|---|
| 30 Tage | 24 Stunden | 8 Stunden | 2 Stunden |

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

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

## Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

## Einschränkungen:
Das Kontrollplasma unterliegt den Einschränkungen der verwendeten Reagenzien und Geräte. Ergebnisse außerhalb des Sollbereichs können verursacht werden durch abgelaufene Materiale, ungültige Methodenkalibration oder Problemen an Reagenz, Gerät oder Zubehör.

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